CASE AUTH/3191/4/19 ***NO BREACH OF THE CODE***

ANONYMOUS v AMGEN

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 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 Amgen Limited. The service sponsored by Amgen was related to bone health.

Amgen marketed Prolia (denosumab) for the treatment of, *inter alia*, osteoporosis in post-menopausal women and in men at increased risk of fractures.

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 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 Amgen:

> **'4 of our 5 regions are currently recruiting Amgen reviews in a handful of CCGs [clinical commissioning groups], but I am pleased to say that Amgen will be releasing some additional CCGs in which we can recruit within the next week or so – more to follow from [name] on this.'**

Another extract from the email (final paragraph), provided to Amgen 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 clients such as [three named companies – not Amgen] 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 the therapy reviews from Amgen 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 either 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 Amgen 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 its comments with regard to the impression of the entire email but noted that the email did not refer to a specific Amgen medicine nor link the Amgen therapy review service to a specific medicine.

The Panel noted Amgen's submission that the aim of the osteoporosis therapy review service was to assist the key long-term goals of osteoporosis management and to support GP practices in the review and implementation of NICE Clinical Guideline 146, which offered best practice advice on the assessment of fragility fracture risk in adults, in order to reduce the risk of fracture complications and disease progression. A further aim was to support GP practices to optimise the care of patients at risk of fragility fractures associated with osteoporosis via medicinal and non-medicinal interventions according to practice defined treatment pathways and current best practice guidelines in defined cohorts of patients. According to the brief to the named third party provider pharmacists, the service was available to practices for which a need had been identified for a review of patients with a confirmed diagnosis of osteoporosis or those at high risk of fragility fractures. Amgen submitted that its representatives were not involved in offering the service. The service was offered to practices by the third party provider staff, for example when working within practices on different projects, when asked if they had any services available that could optimise the care of patients with bone health issues. Additionally, there were several Academic Health Science Networks, CCGs and other NHS regional organisations that encouraged practices to participate in the service. The clinical protocol required practices to complete two options of preferred first line bone sparing agents and two options of the practice preferred second line bone sparing agent with restrictions for each.

The Panel noted the documents provided by Amgen regarding the arrangements as set out below.

The Panel noted that according to Amgen and its documentation each clinical assessment might result in a proposed intervention such as (but not limited to) an invitation for a practice review, a change in dose, preparation or treatment, cessation of treatment or referral to a secondary care osteoporosis clinic. Amgen submitted that the third party service provider pharmacists would only implement the therapeutic review

services and would not recommend a specific pharmaceutical product, write prescriptions or recommend or take any action that did not comply with the approved and signed protocol from the GP. The service was not offered on the condition that any Amgen products would be prescribed and therapy choice arising from the patient review process remained the choice and sole decision of the lead GP.

The Panel noted that Amgen did not appear to provide any product information to the third party service provider pharmacists. Pharmacists involved received internal training on the osteoporosis therapy review service overseen by national and regional lead pharmacists. According to the briefing document, all third party service provider pharmacists involved in the delivery of the therapy review would have received appropriate training and would have a thorough working knowledge of the relevant guidelines and key principles of the management of osteoporosis. Amgen submitted that the staff from the third party undertook regular field visits to ensure company procedures and agreed protocols were adhered to at all times.

The Panel noted the dashboard of anonymised, aggregated service-related data provided by Amgen. The dashboard contained baseline data, including analysis of current bone sparing agent prescribing across aggregated practices by medicine and included data regarding denosumab. An analysis following pharmacist led review was included in the dashboard but made no reference to any specific medicine.

Whilst the Panel had concerns including about how the email portrayed the named third party therapy services and its effect 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 Amgen therapy review with Amgen's products particularly based on the email at issue; denosumab was referred to within the clinical protocol in that treatments, such as denosumab and teriparatide should not be stopped without a specialist review to consider alternative follow-on therapy. However, taking all the circumstances into account, including the Panel's view that Amgen's written arrangements for the review did not appear to constitute a switch to Amgen's 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 osteoporosis therapy review supported by Amgen 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, Amgen 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 Amgen 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 service provider on behalf of a number of pharmaceutical companies, including Amgen Limited. The service sponsored by Amgen was related to bone health.

Amgen marketed Prolia (denosumab) for the treatment of, *inter alia*, osteoporosis in post-menopausal women and in men at increased risk of fractures.

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 repercussions 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 Amgen:

> '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.
>
> …
>
> **Amgen**
>
> 4 of our 5 regions are currently recruiting Amgen reviews in a handful of CCGs, but I am pleased to say that Amgen will be releasing some additional CCGs in which we can recruit within the next week or so – more to follow from [name] on this.'

Another extract from the email (final two paragraphs), provided to Amgen 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 databases]. 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 clients such as [three named companies – not Amgen] 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 the therapy reviews from Amgen 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 stated 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 either 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 was funded by 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 Amgen, 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.

RESPONSE

Amgen explained that the osteoporosis therapy review service was a non-promotional medical service provided by a team of clinical pharmacists employed by the named third party service provider. The aims of the review service were to assist the key long-term goals of osteoporosis management and to support GP practices in the review and implementation of The National Institute for Heath and Care Excellence (NICE) Clinical Guideline 146 in order to reduce the risk of fracture complications and disease progression. Amgen provided a copy of the certified briefing for the service.

Amgen submitted that whilst the service was funded and organised on behalf of the company, therapy choice arising from the patient review process was solely at the discretion of the lead GP. The clinician responsible for the care of his/her patients retained full control over the entire process. The service was not offered on the condition that any Amgen products would be prescribed.

The service provided a full therapeutic review and clinical assessment for individual patients leading to a rational management decision by the GP. This allowed the patient to receive optimal treatment or other non-medicinal intervention as decided by the GP. The third party service provider pharmacists did not suggest and did not implement a switch service which simply changed a patient from one medicine to another without a full clinical assessment.

The protocol (copy provided) detailed the procedures by which the named third party service provider pharmacist clinically assessed patients. Each clinical assessment might result in a proposed intervention such as (but not limited to) an invitation for a practice review, a change in dose, preparation or treatment, cessation of treatment or referral to a secondary care osteoporosis clinic. All proposed interventions were made in accordance with the individual GP practice intervention specification provided within the protocol. All interventions made by the third party pharmacist were made in full accordance with the GP's direction and authority. Full therapy review details were contained within the code of conduct section of the protocol.

When undertaking the reviews in GP practices, the third party service provider pharmacists were directly accountable to the authorising GP and had to work within the confines of the protocol and the clinical stipulations of the authorising GP. These conditions should reflect local health board prescribing protocols (if applicable). The third party pharmacists only implemented the therapeutic review services and would not:

- recommend a specific medicine
- write prescriptions or
- recommend or take any action that did not comply with the approved and signed protocol from the GP.

In its Quality Standard 149 on osteoporosis, NICE recommended that adults who had already sustained or had other high-risk factors for fragility fracture, had an assessment of fracture risk and using FRAX or QFracture. For those with high or intermediate risk of fragility fracture and diagnosed with osteoporosis, NICE recommended that they be offered bone-sparing medicines. NICE also recommended that adults prescribed bone-sparing medicines be reviewed 4 months after starting treatment and annually thereafter. Medication reviews should assess how patients managed their treatment and patients should be asked about adverse effects and treatment adherence. The quality standard also recommended that adults who had been taking bisphosphonates for at least 3 years (iv) and 5 years (oral) should be reviewed for the risks and benefits of continuing treatment.

<u>Operational aspect of the therapy review service</u>:

The protocol must be discussed in detail by the third party service provider pharmacist before its implementation and must be completed in full by an authorised GP and signed by both the prescriber and either a second authorised GP or the practice manager as a prerequisite before any work was undertaken by the third party service provider personnel. Any subsequent alterations to the agreed protocol must be documented and countersigned by the authorising GP.

Once authorised, the third party service provider pharmacist would conduct clinical searches using the GP practice computer system to identify patients meeting the therapy review inclusion criteria as specified and authorised by the GP. This would lead to identification of discreet patient groups that would be presented and discussed with the GP. These discussions would cover clinical screening criteria, disease prevalence data and the third party pharmacist's intervention recommendations. Where the GP concurred with any recommendations and would like the intervention to be implemented by the third party pharmacist, the GP provided authorisation and instruction as to the method by which he/she would like the intervention to be made in accordance with the intervention scope. As detailed above, this might result in a proposed intervention such as (but not limited to) an invitation for a practice review, a change in

dose, preparation or treatment, a cessation of treatment or referral to secondary care osteoporosis clinic.

Each recommended intervention must be detailed and individually approved by the authorising GP.

If the third party pharmacist had been authorised to telephone a patient, he/she would do so in accordance with the approved telephone consultation process. The third party pharmacist, where authorised, would undertake face-to-face consultations to facilitate authorised interventions. Where authorised to do so, the third party pharmacist then completed the intervention by amending the patient's electronic record as applicable and/or issuing the relevant communication to the patient. A thorough audit trail must be maintained at all times to ensure that clinical governance was at the forefront of this patient centred review. Any written materials (copies provided) including patient education leaflets and template letters provided by the third party pharmacist, were pre-approved by Amgen and submitted for approval and signed by the authorising GP before issue. Finally, on completion of the therapy review service, a documentation file was left with the practice.

Briefings from the third party to pharmacists implementing the reviews:

The briefing document to the named third party service provider (copy provided) alongside the clinical protocol (copy provided) formed the basis of the materials used for training for the service and the delivery of the service.

The third party pharmacists were expected to have a thorough working knowledge of the relevant guidelines and key principles of the therapy area as outlined in the briefing document: NICE Clinical guideline 146, Osteoporosis NICE Quality Standard [QS149] April 2017, National Osteoporosis Guideline Group (NOGG) Clinical guideline for the prevention and treatment of osteoporosis.

Amgen noted that registered pharmacists had continuing professional development (CPD) obligations as part of their registration conditions for the General Pharmaceutical Council (GPhC) or the Pharmaceutical Society of Northern Ireland (PSNI). Additionally, the third party service provider's CPD policy asked for 9 CPD entries to be submitted internally to monitor on-going learning. CPD resources were also signposted on internal documents site for all pharmacists to access easily.

Training on therapy review services was conducted via a training cascade led by national lead pharmacists (NLPs) at the third party service provider.

For in-field training, a regional trainer accompanied the third party service provider pharmacist during initial training days and the levels of competence for delivering the service were assessed during field visits by NLPs or regional lead pharmacists (RLPs) using a structured training assessment documented in training records. A sign-off procedure was completed before the third party pharmacists worked unsupervised. After sign-off, quality assurance visits of field-based staff aimed to ensure on-going quality and standardisation. The pharmacists also had to complete training on pharmacovigilance reporting requirements, the Code and clinical and information governance (including data protection/GDPR).

Amgen stated that when it selected any service provider, it conducted extensive due diligence to ensure that the third party abided by all regulations, laws and the Code. In addition, the service agreement with the named third party service provider contained contractual obligations to abide by the Code and all its pharmacists received Code training as part of their CPD requirements.

Amgen initially selected the named third party service provider to develop a therapy review service due to its extensive experience. Details were provided.

Periodically, Amgen had update calls with the third party service provider to ascertain the progress of the therapy reviews and if any issues had arisen. Recently, Amgen internal auditors had reviewed all third party services and there were no findings for this service provider.

Amgen stated that the success of the therapy review service was measured by the number of reviews conducted and public acknowledgements of the benefits received from the therapy review service by patients and the NHS.

Amgen stated that it did not ask the named third party service provider for, and nor did it receive information from it about the proportion of patients changed to Amgen products as this would be an inappropriate metric to provide in relation to a therapy review service. As already detailed above and in the supporting documents, any such interventions were only implemented where they were agreed to or requested by the authorising GP who oversaw the review and many of the recommended medicinal and non-medicinal interventions would be actioned by the practice team or a specialist team to whom the practice might refer a patient, eg to have a DEXA scan.

Amgen discussed the matter with the named third party service provider which confirmed that the confidential internal memo, to which the complainants referred, was received by staff from a number of departments including office-based administrators, finance personnel, IT technicians, office management, human resources, and clinical pharmacists. Amgen understood that this internal communication was intended to ensure that the internal team was up-to-date with current services and the range of services in development.

With regard to the question of ‘client value’, the third party service provider had confirmed that all of its staff were encouraged to talk to NHS staff about the value that the third party’s services delivered to patients and to the NHS. The management team at the third party considered that if therapy review services were valued by patients and NHS staff, then companies were likely to support such work to the extent that they were able. Amgen considered that the service delivered value to both patients and the NHS.

As detailed in the protocol and briefing documents and stated above, whilst Amgen funded the therapy review service, the therapy choice and any intervention arising from the review remained with the GP and the service was not offered on the condition that Amgen medicines would be prescribed. As noted above, clinical assessment could result in a range of proposed medicinal or non-medicinal interventions. The third party pharmacists only implemented the therapeutic review services and would not recommend a specific medicine, write prescriptions or recommend or take any action that did not comply with the approved and signed protocol from the GP. Amgen therefore rejected the complainants’ claim of ‘commercial’ bias.

Amgen further strongly rejected the claim that the therapy review services were not transparent to those who used the services or to patients. The clinical protocol Section 1.3 Declaration of

Sponsorship required 'All documentation relating to this therapy review service must clearly identify Amgen as the sponsoring company and prominently state "This service to medicine is funded by Amgen Ltd and delivered by [named third party service provider]". This declaration of sponsorship must be sufficiently prominent to ensure that readers of sponsored material are aware of it from the outset. The declaration must accurately reflect the nature of Amgen's involvement'.

Patient-facing letter templates all contained the following statement in the first paragraph: 'This therapy review is funded by Amgen Ltd, a pharmaceutical company' and the bottom of the page 'This therapy review is a service to medicine funded by Amgen Ltd and delivered by [named third party service provider]'. Furthermore, at the bottom of each page of the service authorisation form, which was signed by both the lead GP and either a second GP or the practice manager, it was stated that 'This service to medicine is funded by Amgen Ltd and delivered by [named third party service provider]'.

Request for SPC

Amgen noted the Authority's request for copies of any relevant summary of product characteristics (SPC). Whilst the therapy review service was not linked to the prescribing of any particular medicine in favour of any other, it was possible that prescriptions might be changed or initiated within the review. Amgen was obliged to ensure that all the named third party service provider staff were aware of their pharmacovigilance obligations, but it did not provide any product information.

In summary, Amgen refuted that the therapy review services constituted a programme to increase the prescribing of its medicines as alleged. Whilst Amgen funded the service, therapy choice arising from the patient clinical review process remained the decision of the GP and offering of the service was not conditional on the prescribing of any Amgen product. The comprehensive therapy reviews were primarily to enhance patient care and benefit the NHS; they ensured that patients received optimal treatment – non-medicinal and/or medicinal. It was clear in the certified protocols, briefing documents and training materials that the prescribing decision remained with the patient's prescriber.

Amgen submitted that it had not breached Clauses 9.1, 12.1, 19.2 or 2 of the 2016 Code. It had maintained high standards throughout and was not in breach of Clause 9.1. Amgen's actions to support the therapy review service followed Code and supplementary information, including the checks and balances required to ensure such a service was non-promotional, of benefit to the NHS and patients and in line with the clauses listed above.

Amgen denied a breach of Clauses 12.1, as the therapy review service was not disguised promotion and the offer of the service was not conditional on the prescribing of any Amgen medicine.

Clause 19, Medical and Educational Goods and Services (MEGS), clearly stated that a therapeutic review was a legitimate activity for a pharmaceutical company to support and/or assist. The osteoporosis therapy review service offered a range of relevant treatment options (including non-medicinal choices) and was not limited to any Amgen product. The prescribing GP remained in charge of all treatment decisions. Amgen denied a breach of Clause 19 as requirements of this clause and its supplementary information were adhered to in all respects.

Amgen also denied a breach of Clause 2, and whilst this clause related specifically to promotional activity and the therapy review service was not promotional, the company submitted that it had always acted appropriately and in compliance with the Code. Therapy review services were legitimate under the Code if administered in accordance with the safeguards required by the Code and in Amgen's view, it had more than met the standards required.

In response to a request for further information Amgen confirmed that representatives were not involved in offering the service to practices. The service was offered to practices by staff from the third party service provider, for example when a pharmacist working in a practice on a different project was asked if they had any services available that could help to optimise the care of patients with bone health issues. Additionally, there were several Academic Health Science Networks, Clinical Commissioning Groups, and other NHS regional organisations that had encouraged practices in their locality to participate in the service, resulting in practices contacting the third party service provider to arrange participation in the service.

Amgen provided an example of the dashboard containing anonymised, aggregated service-related data it received from the third party service provider regarding the service. Amgen submitted that the data indicated the extensive in-depth data analysis that occurred within the participating practices ahead of discussing the range of interventions, in order to make informed decisions and to improve patient care.

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 Amgen] 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-to-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.

Panel ruling in Case AUTH/3191/4/19

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

The Panel noted Amgen's submission that the aim of the osteoporosis therapy review service was to assist the key long-term goals of osteoporosis management and to support GP practices in the review and implementation of NICE Clinical Guideline 146, which offered best practice advice on the assessment of fragility fracture risk in adults, in order to reduce the risk of fracture complications and disease progression. A further aim was to support GP practices to optimise the care of patients at risk of fragility fractures associated with osteoporosis via medicinal and non-medicinal interventions according to practice defined treatment pathways and current best practice guidelines in defined cohorts of patients. According to the brief to the named third party service provider pharmacists, the service was available to practices for which a need had been identified for a review of patients with a confirmed diagnosis of osteoporosis or those at high risk of fragility fractures. Amgen submitted that its representatives were not involved in offering the service. The service was offered to practices by the third party service provider staff, for example when working within practices on different projects, when asked if they had any services available that could optimise the care of patients with bone health issues. Additionally, there were several Academic Health Science Networks, CCGs and other NHS regional organisations that encouraged practices to participate in the service. The clinical protocol required practices to complete two options of preferred first-line bone-sparing agents and two options of the practice preferred second line bone sparing agent with restrictions for each.

The brief to the third party service provider pharmacists (Background of the disease area) stated that appropriate pharmacological therapy could reduce the risk of fragility fractures and that NICE recommended that adults assessed as at high or intermediate risk of fragility fracture and diagnosed with osteoporosis should be offered bone-sparing medicine treatment. It further stated that NICE also recommended that adults prescribed bone-sparing treatments were reviewed 4 months after starting treatment and annually thereafter. Medication reviews should assess how a person was managing their treatment and patients should be asked about adverse effects and treatment adherence.

The Panel noted that NICE Quality Standard 149 stated that medicines that could be prescribed to prevent fragility fractures include bisphosphonates and non-bisphosphonates and listed Amgen's product denosumab as one of 5 non-bisphosphonate options.

The brief to third party service provider pharmacists further stated that bisphosphonates had been widely used in the treatment of osteoporosis and had been shown to prevent bone loss and reduce the incidence of fractures in patients with osteoporosis. They bind strongly to bone mineral and inhibit bone turnover and the effect lasted for many months after treatment was stopped. Because of these effects there were growing concerns amongst clinicians regarding the potential of increased bone fragility due to the suppression of normal bone remodelling, essential for repair of skeletal micro-damage. In its draft quality standard NICE recommended that adults who had been taking bisphosphonates for at least 3 years had a review of the risks and benefits of continuing treatment.

The Panel noted that the clinical protocol (Background of the disease area) referred to concerns over rare adverse-effects of long-term bisphosphonate treatment such as osteonecrosis of the jaw and that NICE recommended that patients' fracture risk was reassessed after long-term treatment with a bisphosphonate to determine whether treatment should be continued or if the patient would benefit from a 'drug holiday'. The clinical protocol stated that the need for continued treatment should be re-evaluated periodically but other treatments, such as denosumab and teriparatide should not be stopped without a specialist review to consider alternative follow-on therapy.

The brief to the third party pharmacists identified 5 cohorts of patients with proposed actions, 4 of which featured therapeutic optimisation. The fifth cohort were patients identified by 'Attend 2 Fracture' risk tool which was run remotely prior to the onsite review.

The Panel noted that according to Amgen and its documentation each clinical assessment might result in a proposed intervention such as (but not limited to) an invitation for a practice review, a change in dose, preparation or treatment, cessation of treatment or referral to a secondary care osteoporosis clinic. Amgen submitted that the third party service provider pharmacists would only implement the therapeutic review services and would not recommend a specific pharmaceutical product, write prescriptions or recommend or take any action that did not comply with the approved and signed protocol from the GP. The service was not offered on the condition that any Amgen products would be prescribed and therapy choice arising from the patient review process remained the choice and sole decision of the lead GP.

The Panel noted that Amgen did not appear to provide any product information to the third party service provider pharmacists. Pharmacists involved received internal training on the osteoporosis therapy review service overseen by national and regional lead pharmacists. According to the briefing document, all the third party pharmacists involved in the delivery of the therapy review would have received appropriate training and would have a thorough working knowledge of the relevant guidelines and key principles of the management of osteoporosis. Amgen submitted that regular field visits were undertaken to ensure company procedures and agreed protocols were adhered to at all times.

The Panel noted the complainant's concern regarding the statement in the email at issue 'As the business evolves a constant challenge will be to transition and integrate client product/therapy priorities into our internal resource and schedules'.

With regard to 'client value' referred to by the complainants, the third party service provider confirmed to Amgen that its staff were encouraged to talk to NHS staff about the value that the third party services delivered to patients and to the NHS. The management team at the third party service provider considered that if therapy review services were valued by patients and NHS staff, then companies were likely to support such work to the extent that they were able. The Panel noted that the email itself did not refer to client value, it was a term referred to by the complainants. Amgen considered that the service delivered value to both patients and the NHS. The Panel noted that as stated in the clinical protocol the third party service provider pharmacist would record statistics of the review for administrative purposes and analysis by the practice. Upon completion, this anonymised summary data would also be forwarded to Amgen in order that the level of benefit to the NHS and its patients could be monitored.

The Panel noted the dashboard of anonymised, aggregated service-related data provided by Amgen. The dashboard contained baseline data, including analysis of current bone sparing agent prescribing across aggregated practices by medicine and included data regarding denosumab. An analysis following the pharmacist led review was included in the dashboard but made no reference to any specific medicine.

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 effect 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 ICS pharmacists would associate the Amgen therapy review with Amgen's products particularly based on the email at issue; denosumab was referred to within the clinical protocol in that treatments, such as denosumab and teriparatide should not be stopped without a specialist review to consider alternative follow-on therapy. However, taking all the circumstances into account, including the Panel's view that Amgen's written arrangements for the review did not appear to constitute a switch to Amgen's 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 osteoporosis therapy review supported by Amgen 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, Amgen 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 Amgen 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 COMPLAINANTS

The complainants stated they were pleased with a variety of comments in the Panel's comments and ruling as follows:

> The Panel had serious concerns about the impression given by the entire email.
>
> In the Panel's view, Amgen had been let down by it's 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 Amgen therapy review with Amgen's products.
>
> In the view of a senior employee at the 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 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 ponder on the Panel’s strongly worded comments above. These comments were not conducive to therapy review service which was maintaining high standards of Code compliance.

The complainants stressed the point for this appeal that although Amgen 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 service provider.

The complainants disagreed that they had not provided evidence to show that Amgen 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 Amgen 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 Amgen therapy review with Amgen’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 which referred to ALL of the clients within the email. This was of major significance and the complainants requested that the Panel reviewed 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 fervently 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.

What Amgen perhaps did not understand was that within the email, several specific products were named and linked to therapy reviews from other companies. Amgen were named within this email and therefore the email as a whole caused serious concern to the complainants and the PMCPA.

The complainants stated that Amgen had naively partnered with the third party service provider for commercial gain and as the PMCPA had rightly said, Amgen had been let down by them. There must be accountability in this case and under the Code, Amgen were responsible for the actions of the third party and therefore had not maintained high standards.

The complainants maintained 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. 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, the company's responsibility around third parties acting on behalf of the pharmaceutical company and where the accountability lay.

COMMENTS FROM AMGEN

Amgen noted that the complainants, in their email of 26 February 2020, requested the Appeal Board considered the case against Amgen without any substantive additional information. Accordingly, Amgen maintained its position as submitted before the Panel and it respectively submitted its comments to the complainants' allegations.

Amgen understood 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. Amgen consistently adhered to the Code's provisions and maintained that, in the present case, all actions Amgen had taken to support the therapy review service in question were in line with Code procedure and Supplementary Information. In particular, the named third party service provider in the conduct of the therapy review, did not deviate from the Code certified briefing document and clinical protocol. No complaint on the conduct or content of the therapy review service, either during or subsequent to its execution, had been received from any party and it remained to this day a case study in the area of bone health as published on the NICE Shared Learning Zone where an Academic Health Science Network described the benefit to patients and the NHS.

In conducting the therapy review services, the third party service provider pharmacists only conducted the therapeutic review and did not recommend a specific pharmaceutical product, write prescriptions or recommend or take any action that did not comply with the approved and signed protocol from the prescribing GP. The clinician responsible for the care of his/her patients retained full control over the entire process. Amgen therefore rejected the complainants' claim that this service was linked to any Amgen medicine. All the extensive evidence submitted by Amgen and reviewed by the Panel did not find Amgen in breach of the Code.

Amgen believed it was excessive and misleading to conclude, as the complainants suggested, that any single comment within the body of a long and varied internal email must necessarily apply to any and all other persons or entities mentioned within the email, regardless of context. Amgen understood that this internal communication was intended to ensure that its internal team were up-to-date both on current services and also the range of services that were in development. Amgen disagreed with the complainants' assertion that the phrase 'client product/therapy' must be interpreted as referring to (an unnamed) product of a client pharmaceutical company and not a therapeutic area or disease state targeted for a therapy review. This was the more reasonable interpretation of the email in Amgen's view – particularly as arguably the most common meaning of the '/' is 'or' – to denote an alternative. Therefore, Amgen disputed the phrase must link the product of any client pharmaceutical company referenced within the email to its respective therapy review. There was no mention of an Amgen product in the email and Amgen rejected the interpretation that purported to manufacture a link to an Amgen medicine.

Notwithstanding the Panel's concern regarding the tone of the internal third party service provider email and their view that 'Amgen had been let down by their third party vendor, …', the Panel, nevertheless, after review and consideration of all materials and information, found 'the email did not refer to a specific Amgen medicine nor link the Amgen therapy review service to a specific medicine' and there were no breaches of the Code. It was Amgen's position that the complainants had submitted no further material evidence or information to reverse the Panel's findings.

Amgen submitted it would be a perverse outcome to be found in breach of the Code for its support of a therapy review service that fully complied with all aspects the Code and underpinned by national guidance (NICE Quality Standard 149 on osteoporosis). This service had significantly benefitted the NHS and patients and improved the health outcomes for patients at risk of sustaining a fragility fracture, link provided. Amgen believed that it had fully addressed all of concerns, maintained high standards throughout, followed both the letter and spirit of the Code and was in no way in breach of Clause 9.1. As detailed in Amgen's response to the initial complaint when selecting any service provider, extensive due diligence was conducted by Amgen to ensure that the third party abided by all regulations, laws and the Code. All actions Amgen had taken to support the therapy review service (and in the third party's performance of it) had followed Code procedure and supplementary information, including the checks and balances required to ensure such a service was non-promotional, of benefit to the NHS and patients and in line with the Code.

FINAL COMMENTS FROM THE COMPLAINANTS

The complainants referred to part of Amgen's response to the appeal:

> 'In conducting the therapy review services [the third party service provider] pharmacists only conducted the therapeutic review and **did not recommend a specific pharmaceutical product**, write prescriptions or recommend or take any action that did not comply with the approved and signed protocol from the prescribing GP.'

The complainants stated that the third party service provider members within its group of complainants who had conducted this therapy review themselves vehemently disagreed with this. It was a rather confident statement made by Amgen, and the complainants wondered how

it could be so confident of this unless it had a recording of every conversation the pharmacists had with the GPs and it had reviewed the consultation notes of every patient reviewed. The complainants submitted that the Panel had been very clear in its assessment and as a reminder, referred to the following comments:

- The Panel had serious concerns about the impression given by the entire email.
- In the Panel's view, Amgen 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 Amgen therapy review with Amgen's products.
- In the view of a senior employee at the third party service provider, the therapy services carried out by it 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 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.

Amgen disputed that the phrase 'client product/therapy' must link the product of any client pharmaceutical company referenced within the email to its respective therapy review. The PMCPA's comments above were of the opposite opinion which the complainants wholeheartedly supported.

The complainants agreed there was no mention of an Amgen product in the email, however, there did not have to be to warrant a breach. As the Panel had judged: 'On the balance of probabilities, it was not unreasonable that some, if not all, of the [third party service provider] pharmacists would associate the Amgen therapy review with Amgen's products'.

The complainants urged the Appeal Board to consider the following:

- The complaint related to the email in question (14 August 2018) and to request that Amgen was not permitted to detract from it by bringing up other parts of the service for which the complaint did not relate to.
- The PMCPA's comments in relation to the Amgen review complaint were very strong (damning in the complainants' opinion) and warranted a Clause 9.1 breach.

- The established principle under the ABPI 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 believed that although Amgen had been let down by the third party service provider, it was responsible for the actions of its third party. The summation made by the Panel on the Amgen complaint strongly indicated that high standards had not been maintained and a ruling of a breach of Clause 9.1, the least severity of breach, was appropriate.

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 Amgen medicine nor link the Amgen 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 Amgen's documentation was not unreasonable in that it did not appear to link the therapy review service to Amgen'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 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 Amgen medicine. No evidence was provided by the complainants to show that the email in question impacted on the delivery of the Amgen service.

In the Appeal Board's view, Amgen 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 Amgen 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/3193/4/19 Novartis, Case AUTH/3194/4/19 GlaxoSmithKline, Case AUTH/3195/4/19 Chiesi and Case AUTH/3197/4/19 Ethypharm.

Complaint received **30 April 2019**

Case completed **14 October 2020**