CASE AUTH/3193/4/19 ***NO BREACH OF THE CODE***

ANONYMOUS v NOVARTIS

Sponsored therapy review service

An anonymous contactable group, which described itself as consisting of GPs, NHS leaders, pharmacists, NHS patients and current staff from a named third party service provider complained about a number of therapy review services provided by that third party on behalf of a number of pharmaceutical companies, including Novartis Pharmaceuticals Ltd. The service sponsored by Novartis was related to heart failure.

Novartis marketed Entresto (sacubitril and valsartan) for the treatment of symptomatic chronic heart failure with reduced ejection fraction.

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 Novartis:

> **'We have now trained our first pharmacists in Heart Failure as we launch the first joint venture (JVs) in the [named region]. With several other JV projects at the signing stage this should roll out beyond the [named] region after the holiday season.'**

Another extract from the email (final paragraph), provided to Novartis 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 – including Novartis] 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. 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 review from Novartis 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 above (and similar activity) had been 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 treatments changed by the named third party service provider which had a hidden agenda to provide a return on investment to the pharmaceutical companies who paid its wages in order for it to make profit as a business. The NHS and the public need protecting from this.

The detailed response from Novartis 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 it comments with regard to the impression of the entire email but noted that the email did not refer to a specific Novartis medicine nor link the Novartis therapy review service to a specific medicine.

The Panel noted Novartis' submission that to address the well-recognized and significant unmet patient need, Novartis worked with trusts, clinical commissioning groups (CCGs) and GP federations (and an Academic Health Science Network) to help GPs to manage patients with heart failure. The joint working projects all shared the aim to improve the detection and treatment of heart failure in primary care – to improve outcomes for appropriate patients and the health system as a whole.

According to the project initiation document, the benefits of the joint working project for Novartis included the creation of more opportunities for the appropriate use of cardiology licensed medicines in line with NICE and clinical guidelines, including Novartis' medicines.

The Panel noted that NICE guideline 'Chronic heart failure in adults: diagnosis and management' referred to the use of sacubitril valsartan including that treatment with sacubitril valsartan should be started by a heart failure specialist with access to a multidisciplinary heart failure team.

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

The Panel noted Novartis' acknowledgement that the email could have been worded differently but, in this instance, 'product/therapy priorities' did not equate to promotional priorities or objectives. According to Novartis, the product/therapy priorities in these joint-working projects would have included creating awareness of NICE guidelines and identifying patients not treated to such guidelines to allow NHS staff to review their care.

Whilst the Panel had concerns including about how the email portrayed the named third party 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 Novartis therapy review with Novartis products particularly based on the email at issue. However, taking all the circumstances into account, including the Panel's view that the Novartis written arrangements for the

service did not appear to amount to a switch to Novartis' 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 heart failure therapy review supported by Novartis were such that they failed to meet the requirements of the Code. Nor had the complainants provided evidence that the therapy review constituted disguised promotion. The Panel therefore ruled no breach of the Code.

In the Panel's view, Novartis 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 Novartis 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 Novartis Pharmaceuticals Ltd. The service sponsored by Novartis was related to heart failure.

Novartis marketed Entresto (sacubitril and valsartan) for the treatment of symptomatic chronic heart failure with reduced ejection fraction.

COMPLAINT

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

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

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

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

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

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

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

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

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

> '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
>
> …
>
> **Novartis**
>
> We have now trained our first pharmacists in Heart Failure as we launch the first joint venture (JVs) in the [named region]. With several other JV projects at the signing stage this should roll out beyond the […] region after the holiday season.'

Another extract from the email (final two paragraphs), provided to Novartis 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 client such as [three named companies – including Novartis] 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. 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 review from Novartis 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.

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 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 above (and similar activity) had been 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 treatments changed by the third party service provider which had a hidden agenda to provide a return on investment to the pharmaceutical companies who paid its wages in order for it to make profit as a business. The NHS and the public need protecting from this.

When writing to Novartis, 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

Novartis noted that the complaint appeared to be based on an internal email to the third party service provider staff sent on 14 August 2018. The company disagreed with the complainant's view that by describing the need to '… transition and integrate client product/therapy priorities

into their internal resources and schedules' created a commercial bias, by linking therapy reviews to a Novartis medicine in breach of the Code.

Furthermore, taking the wording in question at face value, Novartis stated that it would expect service providers, to be fully informed about the products and therapy areas of the projects it worked on and about the objectives of the projects (in this case joint working projects) that it was contracted for. Without a thorough understanding of the relevant treatment guidelines and available evidence-based treatments, Novartis did not consider that the contracted service provider could effectively meet the needs of the GP practices involved in the joint working projects, the patients involved or the objectives of the projects.

Novartis submitted that the named third party service provider had provided the following rationale for its email:

- The third party aligned its therapy-specific clinical training to the therapy areas in which its clients wished to support its 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.
- The third party used internal communications to ensure that its staff knew about the medicines marketed by its client companies in order that those staff could meet their pharmacovigilance obligations in relation to those products. However, none of the certified service materials used with NHS staff to deliver the third party services made any link to any individual product or product range.
- The third party fervently believed that clinical pharmacists possessed an excellent skill set to deliver services within general practice, something that NHS England had also recognized within the new GP contract. Nevertheless, the third party service provider did not leave product knowledge to chance and alongside its extensive clinical training, it also provided product training on all product options open to a prescriber. This would cover aspects of the summary of product characteristics (SPC) eg contraindications and interactions, product positioning in line with the latest national guidance (usually the National Institute for Health and Care Excellence (NICE)) and the individual pharmacovigilance requirements. The third party viewed this as essential training to avoid clinical risk through potential incorrect advice given to GP prescribers.

Novartis acknowledged that the email could have been worded differently, however, in this case, 'product/therapy priorities' did not equate to promotional priorities or objectives. In the case of non-promotional activities, product/therapy priorities could include therapy area education for NHS staff, projects to implement national guidelines or other evidence-based protocols or generation of data exploring the medicine's real-world use. In the case of these joint-working projects, the product/therapy priorities would have included creating awareness of NICE guidelines and identifying patients not treated to such guidelines to allow NHS staff to review their care.

Novartis submitted that through the third party service provider's contracted involvement with the joint working projects together with the wording from the third party above, it considered that client value meant effective delivery against the responsibilities that the third party had been contracted for, as described in the work order between Novartis and the third party, and the objectives of the joint working project as presented in the project initiation document (see

below). Novartis did not consider that 'client value' as used by the complainants, should be interpreted as promotional value and refuted any suggestion otherwise.

Based on its reading and interpretation of the email at issue, Novartis did not consider that there was evidence of breaches of the Code.

Novartis explained that to address the well-recognized and significant unmet patient need, Novartis worked with trusts, clinical commissioning groups (CCGs) and GP federations (and an Academic Health Science Network) to help GPs to manage patients with heart failure. The joint working projects in question all shared the aim to improve the detection and treatment of heart failure in primary care – to improve outcomes for appropriate patients and the health system as a whole.

There were currently five joint working agreements involving the third party service provider (an overview was provided) but Novartis referred specifically to the project signed with a named Academic Health & Science Network (AHSN) which was born from discussions with health professionals from a named CCG and a named NHS Trust and the AHSN. All the NHS parties involved managed patients with heart failure in the area. The project with the AHSN was entitled 'Excellence in Heart Failure' and its structure, with others being similar, was:

(i) NHS expertise and contribution to:

a) Identify heart failure general practice champions
b) Organisation of heart failure patient optimisation clinics for referred patients for pharmacological and non-pharmacological interventions from GPs and specialists in accordance with current best practice guidelines (NICE Chronic Heart Failure)
c) Project management support
d) Heart failure pathway re-design
e) Virtual multidisciplinary teams to enable specialist initiated pharmacological therapies.

(ii) Novartis contribution – project management and making available to GP practices a number of services, through the named third party service provider, to:

a) Identify potential patients with heart failure through case finding
b) Virtual clinics to triage those identified for patient screening and clinical review
c) initial screening of weight, pulse, blood pressure and medication
d) Educate GPs and other relevant primary care staff on national guidelines for heart failure.

In terms of objectives, the benefits for patents was the primary aim of the initiative, with the NHS and the pharmaceutical partner also seeing appropriate benefits, namely:

(i) For patients**:**

- proactive assessment and earlier detection of heart failure
- greater opportunity for initiation and optimization of evidence-based heart failure therapies

- reduction in non-elective admissions and readmissions through early treatment optimization
- improvement in quality of care.

(ii) For the NHS**:**

- increase in the overall quality of care for heart failure patients
- improvement of patient flow and reduced total number of unplanned admissions and in-patient bed days due to heart failure
- increase in records of prevalence rates in line with national average
- reduction of the care inequality gap
- embedding of the heart failure pathway within GP practice (EMIS) systems to facilitate sustainability of high quality care
- potential wider benefits: if successful, this model of care could be transferred to other areas of chronic disease management
- potential for future spread to other areas within the region.

(iii) For Novartis**:**

- creation of more opportunities for the appropriate use of cardiology licensed medicines in line with NICE and clinical guidelines, including Novartis' medicine
- improved reputation.

As part of the AHSN joint working project, the third party service provider (funded by Novartis) educated GPs based on national guidelines and protocols defined by the relevant local specialists. The third party service provider pharmacists were also involved in database case finding and individual patient case-file review – to triage appropriate patients for further review. The third party service provider pharmacists assessed patients individually and made recommendations for treatment and referrals based on the national and local heart failure management guidelines and the local formulary.

All decisions to change treatment and/or for further referral were made by the GP/specialists on an individual patient basis using their own clinical judgment and expertise in addition to the third party service provider patient assessment.

Materials developed by Novartis and the third party service provider, for NHS staff, described the project, the role of the third party service provider, the services provided by it and disclosure of the third party service provider and Novartis involvement within the joint working project. Examples of these documents included:

- the third party service provider heart failure Prevalence Improvement Service
- Combined Clinical Protocol, which presented the third party services in detail.

Based on this description and the materials provided, and the lack of any link or mention of a specific medicine, Novartis submitted that its role and responsibilities and those of the third party service provider were clearly disclosed and described, did not represent disguised promotion and were appropriate for this and similar joint working projects.

Novartis submitted that the third party service provider was a well-recognized organization of clinical pharmacists that provided services to the NHS and industry related to the management of long-term conditions such as diabetes and heart failure. Novartis contracted the third party to provide the services as described in the Joint Working Project Initiation Document . The specifics of the responsibilities were defined and captured in a Framework Agreement and Work Order between the third party service provider and Novartis.

The Work Order required the third party service provider to deliver patient and NHS orientated services in heart failure and there was no suggestion that these had a promotional intent or a commercial bias in favour of Novartis. This was also reflected in the Heart Failure Prevalence Improvement Service booklet offered by the third party.

The Project Initiation Document reflected all the requirements of the Department of Health (DoH) toolkit and guidance and the Code and there was no suggestion of promotional intent or activity.

As expected from joint working projects, Novartis expected an improvement in evidence based use of medicines, which was defined as an increase in the number of heart failure patients receiving guideline directed therapy. However, this was an overall measure and not broken down to individual treatment options, including Novartis' medicines.

Novartis stated that as required by Clause 20, all transfers of value made by the company in connection with this and other joint working projects would be publicly disclosed.

In relation to the required level of knowledge and competency of staff, the Framework Agreement defined responsibilities related to the third party service provider clinical pharmacists' professional qualifications and details were provided.

In order to meet its contractual obligation, the third party service provider confirmed that its staff undertook accredited training provided by education for health delivered by a leading UK expert in heart failure independent from Novartis (further information was provided). In summary, the course structure, designed for both qualified and unqualified staff working in a community or hospital setting, was:

- identify the causes of heart failure
- assess and investigate patients leading to diagnosis
- apply practical pharmacological and non-pharmacological management
- understand challenges in effective end of life care
- implement best practice including NICE guidelines
- recognize the latest devices used in heart failure management.

In addition, Novartis trained the third party service provider on pharmacovigilance requirements to allow Novartis to fulfil its safety-related responsibilities as a result of contracting the third party for the joint working projects.

In terms of understanding the objectives of the joint working project, the third party service provider was involved in meetings with the joint working NHS partners during the creation of each of the projects and in the development of deliverables required for each project. This involvement ensured that the third party was fully informed of the objectives of the joint working projects and its role within them.

Novartis submitted that through the Framework Agreement and Work Order, it had provided an appropriate and reasonable description of the role and responsibilities of the third party service provider, which related to its role in the joint working projects and were free from promotional or individual product-related objectives. Through high quality and independent medical training, the third party was fully competent to participate in the joint working projects and to deliver against its responsibilities.

Novartis did not consider that any aspect of its contracted relationship or design of the joint working project resulted in disguised promotion or commercial bias as alleged.

The Joint Working Project Initiation Document included the anticipated benefits for patients, the NHS and for Novartis. In terms of measures of success aligned with the patient and NHS objectives, the following were project outcomes and measurement criteria for the project that were collected to help assess its impact:

- Overall increase in heart failure prevalence change (accurate pre/post left ventricular systolic dysfunction cohort) for the GP practices in scope vs the prevalence baseline identified prior to the GP practice level audit (baseline provided by quality and outcomes framework measures)

- Increase in the number of heart failure patients receiving guideline directed medical therapy, against the baseline provided by the National Institute for Cardiovascular Outcomes Research measures.

Novartis and the NHS partners held regular monitoring meetings to verify progress of the project including that the project was being conducted effectively and compliantly.

In terms of Novartis's contractual agreement with the third party service provider, payments were made at specific points, which were all related to progress and completion of activities described in the Work Order. Those milestones were consistent with the description of services and were material to the progress of the JW project. None of the milestones introduced commercial bias or promotional intent, either by Novartis or by the third party.

Neither the third party service provider nor its staff received payments, incentives or bonuses related to medicine prescribing or Novartis performance.

Novartis did not set targets for the initiation of its medicines and did not measure prescribing of Novartis medicines as part of this, or any, joint working project. The third party service provider performance was assessed based on its delivery of milestones as set out within the Work Order.

Novartis stated that it was clear from the information provided above and the related supporting documentation that the heart failure joint working arrangements complied with the requirements of the DoH and the Code.

Novartis submitted that allegations that the therapy review services, as part of the joint working project, were 'misleading, deceptive and unlawful' were completely unfounded as were the claims that the services were linked to client product and were not transparent to the users of the services and to patients. The projects involved close partnership between Novartis, the third

party service provider and the NHS and each party fulfilled its clearly documented responsibilities.

Novartis stated that the complaint, in general, appeared to be based on an inaccurate assumption and unfounded allegation, that independent medical service providers must necessarily promote the medicines of the pharmaceutical companies which engaged their services to make a profit and that wording in an email provided proof of such promotional intent.

However, Novartis considered that the set up and arrangement of the projects in question were a good example of how the NHS and the industry could work together and it maintained that this, and the other joint working projects complied with all the relevant requirements and would provide benefit to patients.

In light of the above, Novartis submitted that its joint working projects and activities had been designed and implemented to the required standards and that no breach of Clauses 19 (as applicable) or 20 had occurred. Novartis had been transparent in its activities and had maintained high standards such that no breach of Clauses 12.1, 9.1, or, consequently, Clause 2 had occurred.

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 Novartis] 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 ICS 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/3193/4/19

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 Novartis medicine nor link the Novartis therapy review service to a specific medicine.

The Panel noted Novartis' submission that to address the well-recognized and significant unmet patient need, Novartis worked with trusts, clinical commissioning groups (CCGs) and GP federations (and an Academic Health Science Network) to help GPs to manage patients with heart failure. There were currently five joint working agreements involving the third party service provider (an overview was provided) but Novartis referred specifically to the project signed with a named Academic Health & Science Network (AHSN) which was born from discussions with

health professionals from a named CCG, a named NHS Trust and the AHSN. The joint working projects all shared the aim to improve the detection and treatment of heart failure in primary care – to improve outcomes for appropriate patients and the health system as a whole.

The Panel noted the definition of joint working in the supplementary information to Clause 20. The Department of Health defined joint working between the NHS and the pharmaceutical industry as situations where, for the benefit of patients, one or more pharmaceutical companies and the NHS pool skills, experience and/or resources for the joint development and implementation of patient centered projects and shared a commitment to successful delivery. Joint working had to be carried out in a manner compatible with the Code and must always benefit patients.

According to the project initiation document, the benefits of the joint working project for Novartis included the creation of more opportunities for the appropriate use of cardiology licensed medicines in line with NICE and clinical guidelines, including Novartis' medicines.

The Panel noted that NICE guideline 'Chronic heart failure in adults: diagnosis and management' referred to the use of sacubitril valsartan including that treatment with sacubitril valsartan should be started by a heart failure specialist with access to a multidisciplinary heart failure team.

The Panel noted Novartis' submission that as part of the AHSN joint working project, the third party service provider (funded by Novartis) educated GPs based on national guidelines and protocols defined by the relevant local specialists. The third party pharmacists were also involved in database case finding and individual patient case-file review – to triage appropriate patients for further review. The third party pharmacists assessed patients individually and made recommendations for treatment and referrals based on the national and local heart failure management guidelines and the local formulary.

The Panel noted that the aim of the heart failure prevalence improvement service was to support GP practices in identifying and assigning appropriate clinical-coding to patients who had diagnosed or undiagnosed heart failure and were not currently managed within the practice Quality and Outcomes Framework (QOF) register. The documentation stated that the service was delivered by the third party service provider on behalf of Novartis as part of a joint working arrangement. There was no name given for the NHS partner.

The heart failure prevalence improvement service was delivered remotely using searches based on clinical codes, medication and diagnostic indicators and clinical markers to identify patients potentially missing from the Heart Failure register.

The combined clinical protocol Attend 2 Heart Failure, HF1 and HF2 dated November 2018 set out the arrangements for the service which consisted of three modules.

Attend 2 Heart Failure was described as performing a baseline evaluation with respect to best practice guidelines (NICE Chronic Heart Failure Guidelines) and HF quality standards. It included GP practice education. HF1 was a pharmacist led patients' notes review and HF2 was a pharmacist led patient facing clinic for HF patients.

The third party service provider pharmacist would complete a clinical assessment of patients medical notes. Each clinical assessment might result in a proposed pharmacological or non-pharmacological intervention such as (but not limited to) an invitation for a GP practice face-to-

face review, with the support of the third party pharmacist where applicable, a change in dose of medication, change in treatment (including change of medication), or cessation of treatment. All proposed interventions would be made in full accordance with the authorizing GP's direction and authority. The GP practice had to define its heart failure management framework including which guidelines to be referred to when forming non-pharmacological and pharmacological intervention recommendations.

The schedule to the work contract between Novartis and the third party service provider in relation to the provision of HF therapy review service with the AHSN listed the heart failure prevalence improvement service and what appeared to be Attend 2 Heart Failure, HF1 and HF2 as services to be provided.

The Panel noted that Novartis' response focused on the Joint Working project with the AHSN. Brief details were given of other projects but not what services were supplied by the third party service provider. The Panel noted that the therapy review service was part of the joint working project.

The Panel noted Novartis' acknowledgement that the email could have been worded differently but, in this instance, 'product/therapy priorities' did not equate to promotional priorities or objectives. According to Novartis, the product/therapy priorities in these joint-working projects would have included creating awareness of NICE guidelines and identifying patients not treated to such guidelines to allow NHS staff to review their care.

The Panel noted Novartis' submission that it would expect service providers, such as the third party service provider, to be fully informed about the products and therapy areas of the projects it worked on and about the objectives of the joint working projects that it was contracted for. Without a thorough understanding of the relevant treatment guidelines and available evidence-based treatments, Novartis did not consider that the contracted service provider could effectively meet the needs of the GP practices involved in the joint working projects, the patients involved or the objectives of the projects.

The Panel noted that the third party service provider's rationale for its email included that it aligned its therapy-specific clinical training to the therapy areas in which its clients wished to support its 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. It further stated that the third party service provider used internal communications to ensure that its staff knew about the medicines marketed by its client companies in order that those staff could meet their pharmacovigilance obligations in relation to those medicines. However, none of the certified service materials used with NHS staff to deliver the third party services made any link to any individual product or product range. The third party service provider stated that it did not leave product knowledge to chance and alongside its extensive clinical training, it also provided product training on all product options open to a prescriber. This would cover aspects of the summary of product characteristics (SPC) eg contraindications and interactions, product positioning in line with the latest national guidance (usually the National Institute for Health and Care Excellence (NICE)) and the individual pharmacovigilance requirements.

Th Panel noted Novartis' submission that it considered that client value meant effective delivery against the responsibilities that the third party service provider had been contracted for, as described in the Work Order between Novartis and the third party, and the objectives of the joint working project as presented in the Project Initiation Document. Novartis did not consider that

'client value' as used by the complainants, should be interpreted as promotional value. The Panel noted that the email itself did not refer to client value, this was a term referred to by the complainants.

The Panel noted Novartis' submission that neither the third party service provider nor its staff received payments, incentives, or bonuses related to medicine prescribing or Novartis performance.

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 service provider 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 Novartis therapy review with Novartis products particularly based on the email at issue. However, taking all the circumstances into account, including the Panel's view that the Novartis written arrangements for the service did not appear to amount to a switch to Novartis' 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 heart failure therapy review supported by Novartis 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, Novartis 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 Novartis 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 appealed the ruling of no breach of Clause 9.1, failing to maintain high standards. The complainants were pleased with the following comments and ruling by the Panel:

> The Panel had serious concerns about the impression given by the entire email.
>
> In the Panel's view, Novartis 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 Novartis therapy review with Novartis's products.

> In the view of a senior employee at the named third party service provider, the therapy services carried out by the third party were inextricably linked to the products of the sponsoring companies.
>
> 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 complaint was specifically based upon the email sent by a senior employee of the 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 [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 stressed the point for this appeal that although Novartis claimed to have been Code compliant itself, 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 Novartis had failed to maintain high standards. The complainants alleged that the email dated 14 August 2018 was enough evidence. Even though a specific Novartis 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 Novartis therapy review with Novartis'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 wanted 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'.

However, contrary to the view of the Panel and the complainants, Novartis stated that it would expect service providers to be fully informed about the products and therapy areas of the projects it worked on and about the objectives of the projects it was contracted for. The complainants declared that there was a difference between sending a credible communication fully informing of all the reviews and therapy areas and sending such a business update implying increased prescribing of the company's medicines. This was a gross error of judgement and Novartis had been ill advised in its attempt to deflect the statement.

Novartis also reported that '[the third party service provider] used internal communications to ensure that its staff knew about the medicines marketed by its client companies in order that those staff could meet their pharmacovigilance obligations in relation to those products'. The complainants maintained 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 products for pharmacovigilance obligations. The complainants requested that the PMCPA take a firm stance on such absurd responses to prevent Novartis bringing the industry into further disrepute. The Panel had already expressed serious concerns about the impression given by the entire email.

Novartis had naively partnered with the third party service provider for commercial gain and as the Panel had rightly said, had been let down by them. There must be accountability in this case and under the Code, Novartis was 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. 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.

Novartis had, of course, produced its 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 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, Novartis' responsibility

around third parties acting on behalf of the pharmaceutical company and where the accountability laid.

COMMENTS FROM NOVARTIS

Novartis stated that it was usual for an appellant to state specific grounds for appeal on which the respondent could comment, but that in this case, the complainants had also provided opinion on comments made by the Panel when it communicated their rulings of no breach. In order to ensure that any comments made by the complainants that did not constitute grounds for appeal did not, by implication, impact on the Appeal Board's perception without Novartis' position being understood, Novartis had also included comments on these aspects of the complainants' letter. Before doing so, Novartis noted that it was important to point out that the **only** reference to Novartis in the email in question was this:

> '**Novartis**
>
> We have now trained our first pharmacists in Heart Failure as we launch the first joint ventures (JVs) in the [named region]. With several other JV projects at the signing stage this should role out beyond the […] region after the holiday season.'

Novartis general comments on the appeal

The grounds for appeal appeared to be mere disagreement with the Panel ruling and focussed on the impression given by the third party service provider email as a whole. The appeal did not bring into question the conduct of the third party services provided on behalf of Novartis. No new evidence had been adduced and no procedural errors by the Panel had been put forward. It would appear that the primary focus of the appeal was on comments made by the Panel that Novartis had been let down by the third party service provider because of the impression given by the email in its entirety, in conjunction with the assertion that Novartis was responsible for third parties acting on its behalf. Novartis noted that the Panel ruled no breach of any clause of the Code, despite making these general comments about the whole of the email. The fact remained that, in the email, the only references to Novartis were in a short paragraph, which mentioned heart failure services. At no point was any mention of, or link to, any Novartis product made directly or indirectly; and there was no suggestion, either overtly or by implication, that Novartis products should be preferentially prescribed as a result of the services provided by the third party.

Furthermore, all evidence submitted to the Panel providing the details of the arrangements for the services clearly complied with the requirements of the Code and with the ABPI/NHS/Department of Health guidance for Joint Working.

Novartis' response to the complainants' opening comments and Panel quotations

Novartis noted that the complainants stated they were pleased with a variety of comments made by the Panel in their comments and ruling. All of the quotations the complainants had cited appeared in a section of the ruling notification letter to Novartis, dated 13 December 2019, entitled 'General Comments'. This section preceded the later section, entitled 'Panel ruling in Case AUTH/3193/4/19' in which the Panel detailed the findings in the Novartis case. Novartis was clear that in the General Comments section, the Panel made a number of background comments and statements about the whole of the third party email at issue. The significant

majority of that email was about the programmes and activities of other companies, some of which did indeed mention the products of other companies.

Novartis submitted that it could not be held to account for the activity of other companies or the impression made by references to them. In the opening paragraph of the 'General Comments' section, the Panel clearly stated that:

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

In the subsequent section, which considered the merits of the Novartis' case, the Panel started by clearly stating:

> '[t]he 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 Novartis medicine nor link the Novartis therapy review service to a specific medicine.'

The Panel ruled no breach of the Code in Novartis' case.

However, Novartis wished to address the following quotations cited by the complainants:

1 The Panel had serious concerns about the impression given by the entire email.

Novartis believed that this comment was made in the context of the entire third party email containing references to other companies' services, and that in some of these references, the products of other companies *were* referred to. Novartis could not be held accountable for the representation of other companies' services in the email. Notwithstanding the email in its entirety, Novartis was only briefly mentioned with reference to heart failure services; no specific Novartis product was referred to directly or indirectly.

2 In the Panel's view, Novartis had been let down by its third party.

Novartis' reasonable belief was that this Panel comment was in relation to Novartis being let down by the third party service provider in terms of the potential reputational impact, and not in relation to Code compliance. In any event, Novartis did not believe that to be let down in such a manner necessarily denoted its own failure to maintain the high standards required by the Code.

In response to Points 1 and 2 above, Novartis further noted that, in the opening line of the Panel ruling specifically with regard to Novartis, the Panel qualified these comments in the following sentence:

> '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 Novartis medicine nor link the Novartis therapy review service to a specific medicine.'

3 On the balance of probabilities, it was not unreasonable that some, if not all, of the third party pharmacists would associate the Novartis therapy review with Novartis's products.

Despite commenting on the potential for this association, the Panel was clear that it did not believe that there was evidence that the email demonstrated that the heart failure review service

provided by Novartis failed to meet the requirements of Clause 19.1. As a result, no breach of Clause 19.1 was ruled and Novartis contended that this statement had no bearing on the appeal of no breach of Clause 9.1.

4 In the view of the author of the email, the therapy services carried out by the third party service provider were inextricably linked to the products of the sponsoring companies.

5 In the Panel's view, the email in question might be seen by the third party pharmacists as instructions on how the therapy reviews should be conducted.

Novartis believed that these comments were made in the context of the third party service provider email in its entirety, where some companies' products were mentioned in relation to their services. However, at no point in the email was there any mention or link to any Novartis product, made directly or indirectly and there was no suggestion, either overtly or by implication, that Novartis' products should be preferentially prescribed as a result of the services. Furthermore, the evidence submitted by Novartis to detailing the written arrangements fully complied with all requirements of the Code.

6 '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'.

7 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.

Novartis wished to clarify these quotations explicitly referred to the cases where the third party service provider email expressly linked services to particular products. Further, at no time did the email mention any Novartis product; accordingly, Novartis believed that this comment had no bearing on its specific case, and subsequently, no breaches were ruled by the Panel.

In summary, although the complainants stated that:

> '… the Appeal [Board] ponder on the Panel's strongly worded comments above. These comments are not conducive to a therapy review service which is maintaining high standards of Code compliance',

Novartis firmly believed that the Panel's comments cited were made in relation to the third party service provider email in its entirety, specifically where other companies' products were mentioned. Accordingly, they could not have any bearing on the specifics of the Novartis case and, in particular were not relevant in the consideration of an appeal against the ruling of no breach of Clause 9.1. When the complainants went onto set context, Novartis noted that they made an extremely broad and unfounded allegation, which was not made in the initial complaint. The complainants alleged that:

> '… protocols and documents for an industry sponsored therapy review are never going to be found to make any link to the increased prescribing of the product of the sponsoring company.

> They will always be produced to refute any claims of bias and to avoid any reprimand. What the [complainants] are exposing is what goes on behind the official paperwork.'

Novartis was extremely concerned that this broad sweeping allegation was made with no regard to the evidence in relation to Novartis; further, it would suggest that it had no bearing on the appeal decision in Novartis' case. Documentation and protocols were used, amongst other purposes, to provide an auditable record documenting intent and demonstrating adherence to due process. The documentation adduced to the Panel by Novartis did, indeed, substantiate such intent and adherence. It was unconscionable to allege that some tangential or additional agenda existed beyond the available evidence pertaining to Novartis.

The complainants went onto state that they had:

> '…uncovered an email which exposes the true relationship between [the third party service provider], an 'independent' clinical service provider and the products of their clients.'

Novartis reiterated that at no point in the email was any Novartis product mentioned either directly or indirectly and that this was explicitly acknowledged in the Panel ruling. Novartis contended that this statement had no bearing in an appeal against a ruling of no breach of Clause 9.1.

Novartis' comments on the complainants' specific grounds for appeal:

1 The complainants would like to stress the point for this appeal that although Novartis claim to have been Code compliant themselves, it is an established principle under the Code that pharmaceutical companies are 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.

Novartis agreed that this was an established principle in the operation of the Code. If the third party service provider undertook any activity on Novartis' behalf which resulted in any linkage to a Novartis product, it would, indeed, need to answer to the PMCPA on the basis of that specific situation and any evidence submitted. The fact remained, however, that although both Novartis and the Panel acknowledged that the wording of the email could have been worded differently – and that, in some instances, the products of other companies were mentioned – no mention of any Novartis product was made either directly, or indirectly. Novartis did not believe that the references to other companies' products were made by the third party service provider on its behalf or in relation to its heart failure service, and thus, regardless of the impression given by other sections of the email, it did not substantiate Novartis' failure to maintain high standards.

2 'Even though a specific Novartis 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] pharmacists would associate the Novartis therapy review with Novartis's products". This conclusion alone is damning enough, on the balance of probabilities, to rule a breach of clause 9.1 in the Board's opinion'.

In addition to Novartis' comments on Point 1, above, concerning the impression of the third party service provider email in its entirety, Novartis did not agree with the position 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 Novartis therapy review with Novartis's products'.

This was pure conjecture; indeed, Novartis contended that in other sections of the third party service provider email some companies' products were explicitly mentioned alongside the third party's services, whereas in the reference to Novartis, no product was mentioned. Novartis stood out as explicitly not having any product linked to the services.

Novartis was extremely concerned about any precedent that might be set by a ruling which, by implication, stated that the mere fact it had a heart failure service as a part of a formal Joint Working arrangement meant that the service was linked to any product it had in that therapy area simply by association with the third party service provider email. Clause 19 of the Code explicitly permitted Medical and Educational Goods and Services, which enhanced patient care or benefitted the NHS and maintained care and that clause gave clear stipulations as to the requirements of such arrangements. Clause 20 of the Code allowed Joint Working between one or more pharmaceutical company and the NHS and others carried out in a manner compatible with the Code and also gave clear stipulations as to requirements. Novartis was not ruled in breach of any of these clauses, and the complainant had not appealed any findings in relation to the conduct of the services by third party on behalf of Novartis. Novartis therefore believed that the quotation above could not be evidence of Novartis having failed to maintain high standards in relation to their obligations under the Code either directly or as a result of the actions of the email.

3 The complainant's wish, for this appeal, to boldly highlight the following phrase which is the focus of the complaint: **"integrate client product/therapy priorities"**. This phrase which referred to ALL of the clients within the email. This is of major significance and we would like the Panel to review the wording again. Client product/therapy does not mean therapy area or disease area, it means product of the client and therefore links the product of any client referenced within the email to their respective therapy review'.

Novartis respectfully disagreed that 'product/therapy area priorities' must mean product. In its ruling, the Panel had acknowledged 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.'

Commercial interests of companies were not limited to the promotion of a specific medicine. For example, a therapy area priority for a company might be to work with the NHS to improve the management of a given condition in line with current expected standards of care or independent guidelines. Such activity would ultimately create a health service more able to optimally use all treatment options and did not, in any way, promote the choice of a specific

medicine. Novartis contended that, in its specific case, reference to it in the third party service provider email was only in relation to heart failure services, and that Novartis 'product/therapy area priorities' were to deliver such a heart failure service fully compliant with the Code and in line with ABPI/NHS/DoH guidelines on Joint Working. The documentation provided by Novartis demonstrated that the service offered and instructions to service providers were clear and appropriate, as was the training provided in relation to the same. As a result, subsequent rulings of the Panel found Novartis not to be in breach of the Code; Novartis' service was not found to relate to a specific medicine. Novartis could not, therefore, see how reference by the complainants to the phraseology of the Panel in this regard could constitute evidence of Novartis' failure to maintain high standards.

4 However, contrary to the view of the PMCPA Panel and the complainant, Novartis stated that they would expect service providers to be fully informed about the products and therapy areas of the projects it worked on and about the objectives of the projects it was contracted for. There was a difference between sending a credible communication fully informing of all the reviews and therapy areas and sending such a business update implying increased prescribing of the company's medicines. This was a gross error of judgement and Novartis has been ill advised in its attempt to deflect the statement.

Novartis agreed that if any communication sent by the third party service provider to its employees implied increased prescribing of a company's medicines, it would be inappropriate. If such an action were taken on behalf of a company, that company should answer to the Code in that regard. However, this was not the case with Novartis; the communication merely informed the third party service provider staff that pharmacists had been trained on heart failure as the first Joint Venture was launched and that further Joint Venture projects should roll out in future. With regard to the appeal of a finding of no breach of Clause 9.1 of the Code, Novartis could not see that the email provided evidence of Novartis' failure to maintain high standards.

Novartis was concerned that in their grounds for appeal, the complainants were confusing the content of the third party service provider email (where no communication was made about Novartis products whatsoever) with the information Novartis gave in its response about how and why the staff of the third party were trained in relation to Novartis contractual work. As a reminder, in its response to the initial complaint, Novartis outlined that 'In order to meet their contractual obligation, [the third party] confirmed that their staff undertook [accredited training provided by a named organisation] and delivered by a leading UK expert in Heart Failure independent from Novartis'. More information on this course was provided in Novartis' response to the initial complaint.

In summary, the course structure, which was designed for both qualified and unqualified staff working in a community or hospital setting, was as follows:

- Identify the causes of heart failure.
- Assess and investigate patients leading to diagnosis.
- Apply practical pharmacological and non-pharmacological management.
- Understand challenges in effective end of life care.
- Implement best practice including NICE Guidelines.
- Recognise the latest devices used in heart failure management.
- In addition, Novartis provided the third party service provider with training about pharmacovigilance requirements to allow Novartis to fulfil its safety-related responsibilities for the JW projects.

Novartis did not believe that it was ill-advised in providing information pertaining to the third party service provider's training to fulfil their contractual obligations to Novartis, which was done so in full transparency and to ensure that the Panel had all of the information required to make its ruling.

Furthermore, Novartis believed the arrangements for such high quality and independent training showed that it both strove to, and maintained, high standards.

5 Novartis also report that "[the third party] used internal communications to ensure that its staff knew about the medicines marketed by its client companies in order that those 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 products for pharmacovigilance obligations. The complainant's requested that the PMCPA took a firm stance on such absurd responses to prevent Novartis bringing the industry into further disrepute. The Panel has already expressed serious concerns about the impression given by the entire email.

Novartis pointed out that it did not report that:

> '[the third party service provider] used internal communications to ensure that its staff knew about the medicines marketed by its client companies in order that those staff could meet their pharmacovigilance obligations in relation to those products.'

This was a quotation that Novartis provided directly from a statement issued to it by the third party service provider detailing rationale for the email. Novartis recognised that, regardless of the opinions of the complainant, it was a regulatory obligation as a part of Good Pharmacovigilance Practice, that a pharmaceutical company reported any spontaneously reported (un-solicited) adverse events reported to the company or to vendors acting on their behalf. In order to comply with such obligations, some level of training and awareness of the relevant products of all companies that the third party provided services to would inevitably be necessary for third party staff working on those services. This could not, therefore, be either *'ludicrous'* or *'absurd'* as the complainants suggested, but was a statutory requirement. Notwithstanding its understanding of this need, Novartis maintained that this could not apply to its specific situation of an allegation of failing to maintain high standards with regard to the contents of the email. No Novartis product was mentioned or referred to in the email for pharmacovigilance training purposes or otherwise.

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

Novartis respectfully referred to its previous argument about the appropriate commercial objectives of working in partnership with the NHS and others for the benefit of patients in Joint Working projects. Novartis referred to its previously stated position that to be let down by the third party service provider with regard to the potential over-arching tone of the email was not the same as being let down in terms of Code compliance. The facts, evidence and merits of the specific case against Novartis did not demonstrate a failure to maintain high standards.

7 The complainants maintained that it must not be possible for a pharmaceutical company to partner with an "independent" service provider and an email of this nature 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 may also serve as a warning to other pharmaceutical companies and service providers wishing to partner in this manner, to show that this kind of behaviour would not be tolerated.

Novartis agreed that compliance with the Code, including Clause 9.1, must be maintained and that consequences in breaching the Code should be made where breaches in fact do occur. This included any activity conducted by a third party on behalf of a company. However, Novartis respectfully referred to its earlier position concerning the nature of the email and the nature of references to Novartis. No Novartis product was mentioned directly or indirectly in the email and Novartis could not be held accountable for sections of the third party service party email which related to activities conducted by the third party on behalf of other companies. Further, the complainant provided no evidence to support Novartis' failure to maintain high standards other than conjecture.

8 Novartis had, of course, produced its protocols and briefings to the Panel which show 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 the 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 PMCPA's Panel around the email in question supported this'.

Novartis referred to its earlier arguments concerning the use of documentation as an auditable record of intent and conduct in relation to its activities. Novartis was correctly reflecting its position in relation to the requirements of the Code and had provided physical documentary evidence that it had maintained high standards. Other than the third party service provider email – which only referred to Novartis in relation to the provision of training in heart failure for its heart failure services, and in which no mention of Novartis products were made directly or indirectly – no other evidence had been provided by the complainant to prove, on the balance of probabilities or otherwise, that Novartis had failed to maintain high standards.

Novartis knew that the Appeal Board would conduct a fair appeal hearing, as requested by the complainants, and looked forward to the opportunity to describe its position and answer any questions from the Appeal Board. Novartis agreed with the complainants in their comments that this process was an important part of protecting the NHS, clinicians and their patients by upholding the Code. Not only was Novartis a proactive and ardent participant in self-regulation processes and procedures, but it strove to partner with the NHS and others to ensure that patients could access its medicines appropriately in order to get the best care for them, and the best outcomes for them and the healthcare system.

FINAL COMMENTS FROM THE COMPLAINANTS

The complainants submitted that Novartis wrote that it 'cannot be held to account for the activity of other companies or the impression made by references to them'. The complainants disagreed, 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. From Novartis' letter which included: 'Novartis would like to point out that we did not report that "[the third party service provider] used internal communications to ensure that its staff knew about the medicines marketed by its client

companies in order that those staff could meet their pharmacovigilance obligations in relation to those products"'. This was a quotation that the complainants provided directly from a statement issued to them by the third party service provider detailing rationale for their email. The complainants commended Novartis for pointing out that it was not themselves but the third party who wrote this explanation. Although no doubt embarrassing for Novartis to have used it, it was at least written by the third party which was exactly the sort of contemptuous response many in the industry had grown accustomed to.

The complainants had no interest in getting involved in further semantics with Novartis. Novartis was implicit in the email even though its product was not mentioned by name. The complainants submitted that the Panel had serious concerns about the impression given by the whole email and the complainants respectfully urged the Appeal Board to consider a Clause 9.1 breach in light of the Panel's concerning comments regarding the Novartis complaint.

FURTHER COMMENT FROM THE COMPLAINANTS ON SOME NOVARTIS MATERIAL

The complainants submitted that the two enclosures provided by Novartis were pointless and irrelevant. One document was a brochure from the third party service provider. The other was an Introduction to Heart Failure one-day practical workshop. The complainants were of the opinion that Novartis had treated the PMCPA process with contempt by submitting these documents. The complainants stressed that it was highly relevant for the full Therapy Review Protocols, Pharmacist Briefing Documents, Sales Force Briefing Documents, Service Introduction Documents and all other documents concerning the therapy review for example – results presentation dashboards, final reports, etc to be supplied. The complaint was with regard to the email dated 14 August 2018 which related to the therapy review services and therefore the documentation relating to the therapy review services must be produced. The documents were widely used by the third party service provider, the NHS and pharmaceutical company sales teams so there was every reason to supply them.

FURTHER RESPONSE FROM NOVARTIS

Novartis acknowledged the complainants' response, but with respect, it deferred to the decision made by the independent referee who determined that disclosure was only required for two documents. In any event, the complainants had failed to adduce any further evidence to support the need for disclosure of commercially sensitive material, other than opinion and/or conjecture.

FURTHER FINAL COMMENTS FROM THE COMPLAINANTS

There were no further final comments from the complainants.

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

In the Appeal Board's view, Novartis 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 Novartis 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/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**