CASE AUTH/3188/4/19

ANONYMOUS v BAYER

Sponsored therapy review services

An anonymous, contactable group, which described itself as consisting of GPs, NHS leaders, pharmacists, NHS patients and current staff from a named third party providing therapy review services, complained about a number of therapy review services provided by that third party on behalf of a number of pharmaceutical companies, including Bayer. The complainants referred to two services from Bayer, one related to atrial fibrillation and the other related to coronary artery disease/peripheral artery disease.

Bayer marketed Xarelto (rivaroxaban) used in the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack. Xarelto was also indicated for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.

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 Bayer:

> **'Bayer are committed to the Xarelto (rivaroxaban) AF [atrial fibrillation] review for 2018 with a focus on [name] clinics. Their strategic focus is to push for a licence extension of Rivaroxaban into coronary artery disease (CAD) and Peripheral artery disease (PAD) and have reported excellent clinical trial data to support this application. We have already submitted a proposal for a new review to support these new indications and are hopeful of adding this second service into the [name] portfolio over the coming months.'**

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

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

The complainants stated that the email clearly and indisputably linked the atrial fibrillation therapy review service to Xarelto; a clear and serious breach of the Code.

The clinical team to whom the email was sent was a team of pharmacists employed by the named third party service provider to deliver therapy review services to GP practices. The complainants stated that Code compliant therapy review services must not be linked or biased in any way towards the sponsoring company's medicine(s) and the email above exposed the product bias inherent within the named third party service provider. The email went directly to the clinical team, influencing it and setting the expectation for client product, to fulfil the company need to demonstrate an increase in prescribing of the product of the sponsoring company following delivery of a therapy review service.

The complainants alleged a breach of Clause 2.

Similar comments were made about the coronary artery disease/peripheral artery disease therapy review service and its link to rivaroxaban.

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

The complainants stated that the matter was being reported to the NHS Counter Fraud Authority. The activities would soon be highlighted in the pharmaceutical and

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

The detailed response from Bayer 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.

The Panel noted the complainants' view that Bayer had two therapy review services under the umbrella term 'atrial fibrillation review' referred to within the email in question.

The Panel noted Bayer's submission that it had funded and launched two therapy review services, delivered by the named third party service provider, to support the NHS and patients with atrial fibrillation (AF) at risk of stroke. The AF therapy review services were firstly a Stroke Prevention in Atrial Fibrillation (SPAF1) therapy review service (launched in 2012) and secondly an Anticoagulation Support Clinic (ASC2) (launched in 2015).

The Panel noted that the email which was the subject of the complaint referred to ASC2 clinics. The Panel further noted that Bayer decided to withdraw SPAF1 in May 2018, prior to the date of the email in question (14 August 2018). However, SPAF1 reviews already booked were honoured. By 27 September 2018, SPAF1 was terminated and funding withdrawn. ASC2 then became the only active AF-related therapy review service funded by Bayer and delivered by the third party service provider and remained so. The Panel considered that the complainants had not discharged their burden of proof that the email in question referred to SPAF1. In the Panel's view, the reference to atrial fibrillation review in the email was in relation to ASC2 only. The Panel therefore decided it would not consider SPAF1.

The Panel noted Bayer's disappointment that the email at issue referred to Xarelto in the context of the ASC service. Bayer submitted that an error was made by the named third party service provider in this regard and the reference to Xarelto was inconsistent with the legitimate objectives and approved name of this therapy review service. Further, the third party service provider had acknowledged that it had made an error in this instance, and it was not a name for the service recognised or used within that organisation.

The Panel noted Bayer's submission that the ASC service aimed to improve patient outcomes in conditions associated with anticoagulation use such as stroke prevention in atrial fibrillation (AF). It aimed to ensure patients, authorised by the responsible clinician, received optimal treatment from a comprehensive range of appropriate treatment choices following a pharmacist-led clinical review by a third party service provider pharmacist. According to ASC2 clinical protocol (March 2017), the service aimed to achieve its objective by, *inter alia*, ensuring that the prescribing of non-VKA oral anticoagulants was appropriate for the patient on the basis of approved indications,

patient suitability and avoiding interruption of therapeutic anticoagulation during the transition.

The Panel noted that in its response Bayer referred to its approved clinical protocol for the ASC2 service (March 2017), the brief to the pharmacists (November 2016) and the service contract between the named third party service provider and Bayer plc (May 2012). These were the documents reviewed by the Panel as in its view they were relevant at the time the email in question was sent (August 2018).

The Panel noted the above documents and other relevant documents provided by Bayer regarding the arrangements as set out below.

Whilst the Panel had concerns about how the email portrayed therapy services and the link of the ACS service supported by Bayer to its product Xarelto, it nonetheless noted that the complainants bore the burden of proof. In the Panel's view, it was not unreasonable that some if not all of the named third party service provider pharmacists would associate the Bayer therapy review with Bayer products and in the particular circumstances of this case would link the Bayer therapy review to Xarelto based on the email at issue. However, taking into account all of the circumstances including the Panel's view that Bayer's written arrangements for the service did not appear to amount to a switch to Bayer medicines, the Panel did not consider that the complainants had established, on the balance of probabilities, that the arrangements for the ACS therapy review supported by Bayer were such that they failed to meet the requirements for medical and educational goods and services in the Code. Nor had the complainants provided evidence that the therapy review constituted disguised promotion. The Panel therefore ruled no breaches of the Code.

In the Panel's view, Bayer had been let down by its third party in that the email at issued implied that the review was linked to Bayer's product Xarelto.

The Panel noted that Bayer appeared to have in place the appropriate documentation that did not link the therapy service to its product. The Panel noted, however, that it was a well-established principle that a company was responsible for the acts or omissions of its agents or third parties. If this were not the case companies would be able to rely on such acts or omissions as a means of circumventing the requirements of the Code. In the Panel's view, the email at issue was instructing the third party service provider's pharmacists in relation to a therapy review service for which Bayer was responsible and linking the service to Bayer's product Xarelto. The Panel considered that high standards had not been maintained in this regard and ruled a breach of the Code.

The Panel did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and reserved for such use. The ruling of no breach of Clause 2 was upheld following an appeal from the complainants.

Regarding the CAD/PAD service, the Panel noted Bayer's submission that it only ever received a proposal from the third party service provider in relation to supporting the NHS and patients in this disease area. There was not and had never been a contract for services with the third party to commence any work on a CAD/PAD service; according to

Bayer, no concept document or service documentation had ever been drafted or approved.

Whilst the Panel had concerns about the email at issue in this regard, there was no evidence before it that Bayer had commissioned a therapy review service with regard to CAD/PAD or linked it to rivaroxaban and no breaches of the Code were ruled including Clause 2. The ruling of no breach of Clause 2 was upheld following an appeal from the complainants.

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 Bayer. The complainants referred to two services from Bayer, one related to atrial fibrillation and the other related to coronary artery disease/peripheral artery disease.

Bayer marketed Xarelto (rivaroxaban) used in the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack. Xarelto was also indicated for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.

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 Bayer:

> '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
>
> …
>
> **Bayer**
>
> Bayer are committed to the Xarelto (rivaroxaban) AF [atrial fibrillation] review for 2018 with a focus on [ASC]2 clinics. Their strategic focus is to push for a licence extension of Rivaroxaban into coronary artery disease (CAD) and Peripheral artery disease (PAD) and have reported excellent clinical trial data to support this application. We have already submitted a proposal for a new review to support these new indications and are hopeful of adding this second service into the [the named third party service provider] portfolio over the coming months.'

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

> 'In addition to the range above we continue to hold large advance payments for our BGTS and PN clients who are all looking to us to do more between now and the end of the year to generate bookings against the many practice opportunities listed in [named database].

> These reviews should not be devalued as simple cost cutting as when done well, they offer a range of great clinical outcomes for practices and patients alike.
>
> As the business evolves a constant challenge will be to transition and integrate client product/therapy priorities into our internal resource and schedules. The addition of new clients such as [three named companies – not Bayer] 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 stated that the email clearly and indisputably linked the atrial fibrillation therapy review service to Xarelto; a clear and serious breach of the Code.

The clinical team to whom the email was sent was a team of pharmacists employed by the named third party service provider to deliver therapy review services to GP practices. The complainants stated that Code compliant therapy review services must not be linked or biased in any way towards the sponsoring company's medicine(s) and the email above exposed the product bias inherent within the third party. The email went directly to the clinical team, influencing it and setting the expectation for client product, to fulfil the company need to demonstrate an increase in prescribing of the product of the sponsoring company following delivery of a therapy review service.

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 referred to a job title at the named third party service provider which was responsible and accountable for all therapy review services and Code compliance. The email was not retracted. The complainants alleged a breach of Clause 2.

Similar comments were made about the coronary artery disease/peripheral artery disease therapy review service and its link to rivaroxaban.

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

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

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

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

the pharmaceutical companies which paid its wages in order for it to make profit as a business. The NHS and the public needed protecting from this.

On receipt of the initial response from Bayer the case preparation manager ruled no *prima facie* case to answer in relation to the coronary artery disease/peripheral artery disease therapy review service. The parties were so advised. The complainants did not accept the case preparation manager's view and provided further information (see below). The matter was therefore referred to the Panel as required by Paragraph 5.5 of the PMCPA Constitution and Procedure.

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Complaint – additional information

The complainants provided further information stating that Bayer was an existing long-standing client of the named third party service provider and had sponsored and launched at least three therapy review services to date with the third party. Bayer had received a proposal from the third party for the coronary artery disease/peripheral artery disease service and from the email at issue it was clear that the intention was to deliver a new review and support Bayer's strategic focus of rivaroxaban in coronary artery disease/peripheral artery disease.

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

According to the complainants, it was clear that Bayer and the third party were in the stages of forming a service with the intent of supporting Bayer's strategic focus with its product, rivaroxaban. The complainants referred to the email at issue as the 'proverbial loaded gun' and requested that the PMCPA set a precedent by taking firm action on the unacceptable conduct which discredited the industry and brought it into disrepute.

The complainants stated that importantly, Bayer was in contact with the third party regarding the coronary artery disease/peripheral artery disease service. If a client had no contact with the third party, then one could understand a client having no case to answer but Bayer was fully accountable in this case.

The complainants stated that Bayer had two therapy review services which covered the term 'atrial fibrillation review'. The complainants noted that the case preparation manger had referred the anticoagulation support clinic service to the Panel. The other review, known as the 'Stroke prevention in atrial fibrillation review' was also included in the term 'AF review' used in the email at issue. The complainants wanted confirmation that both reviews were referred to the Panel.

When writing to Bayer, the Authority asked it to consider the requirements of Clauses 2, 9.1, 12.1 and 19.2 of the 2016 Code. Attention was drawn to the supplementary information of Clause 19.1. Relevant extracts of the email were provided to the company and not the complete email.

RESPONSE

Bayer submitted that it had funded the pharmacist-led anticoagulation support clinic (ASC) service which was a legitimate medical service provided by a team of UK registered pharmacists employed and trained by the named independent third party service provider. The ASC service aimed to improve patient outcomes in conditions associated with anticoagulation use such as stroke prevention in atrial fibrillation (AF). Xarelto was a direct oral anticoagulant (DOAC) and was one in a group of many other anticoagulants available for use in appropriate patients requiring anticoagulation within its licensed indication.

The therapy review process for ASC, as documented in the ASC2 clinical protocol (March 2017) instructed the named third party service provider and its pharmacists on how to implement the service to a compliant standard as approved by Bayer. Selection of patient cohorts eligible for the service was achieved by either the authorising clinician/healthcare organisation (HCO) or generated by the third party pharmacist based on the approved cohort criteria (detailed in the ASC2 brief to the pharmacists (November 2016)) and in line with the therapy review process referred to above. Irrespective of how eligible patient cohorts were identified for a therapy review, the patient cohort and mechanism of implementing the ASC service must be authorised by the lead clinician or HCO before implementation. Bayer also noted that, prior to a review, the authorising clinician pre-specified, to the third party pharmacist, his/her preferred anticoagulant for stroke prevention in atrial fibrillation and this specification directed the reviewing pharmacist's review and recommendations in relation to therapy interventions (as outlined in the ASC2 clinical protocol, March 2017).

Depending on the method authorised by the responsible clinician or HCO, pharmacists could then invite authorised patients that consented to the service, for a pharmacist-led consultation involving patient level education and a clinical review. The third party pharmacists then provided the authorising clinician or HCO with intervention recommendations based on their clinical assessment and the responsible clinician/HCO must authorise any subsequent intervention prior to its implementation.

The ASC2 clinical protocol dated March 2017 instructed the third party pharmacists that full control of the entire process and patient-prescribing decision lay with the responsible and authorising clinician or HCO, so the authorising clinician or HCO maintained full autonomy and control of the service provision, including the final decisions made for their patients.

In the ASC2 brief to the third party pharmacists, dated November 2016, they were instructed to possess clear signed permission, in the form of a completed authorisation form from the authorising clinician or HCO before providing the service. They also had to discuss the clinical protocol for the service with the authorising clinicians before the therapy review.

Bayer provided further details on the therapy review process in the ASC2 clinical protocol (March 2017) and the ASC 2 brief to the third party pharmacists (November 2016).

Bayer acknowledged that the PMCPA had requested all relevant documentation, bearing in mind the supplementary information to Clause 19.1. Other relevant materials required for the provision of the ASC service were provided. The company submitted evidence of its due diligence on making sure the third party service provider complied with its Code obligations. Qualifications of final signatories related to the programme were also provided.

Bayer stated that the original brief to the third party pharmacists (dated November 2016 and certified April 2017) was successfully recertified before its recertification due date in April 2019.

However, several additional materials which were contained as appendices in the original brief and due for recertification had, for this latest iteration, been separated out and certified as individual items between March and May 2019. The recertification dates for some materials fell beyond the April 2019 due date. Separating out the appendices as individual items was done to support the third party pharmacists to deliver the ASC service more efficiently.

Bayer acknowledged a lapse in recertifying certain relevant materials and took such matters very seriously. The company intended to issue all recertified ASC materials before withdrawing the previous versions wholesale, without disrupting scheduled clinic reviews and compromising patient outcomes. Despite the company's intentions and prioritisation efforts, there was an unfortunate delay in recertifying certain relevant materials, withdrawing expired versions and circulating the latest versions of relevant materials with the third party for its immediate implementation. Bayer would put in place an appropriate corrective action, preventive action plan to ensure that this issue did not happen again.

Bayer stated that as of 31 May 2019, all relevant materials in use by the third party for the delivery of the ASC service were certified. The company appreciated that the complaint had fallen within the period of recertification of relevant materials. Therefore, for transparency, it had provided copies of both previous and current versions of relevant materials. There had been no changes to the core conduct of the ASC service. Key changes between previous and current versions included: update to the declaration of confidentiality section in the clinical protocol; amendments to ensure consistency in the wording across all documents regarding Bayer's involvement with the ASC service; consolidation of previous patient invite letter templates to two templates and creation of a template to invite patients who had not responded to an initial invite.

Bayer noted the complainants' allegation that the named third party service provider had indisputably linked the atrial fibrillation (AF) therapy review service with Xarelto to the clinical team.

The ASC service funded by Bayer was a therapy review service that aimed to ensure patients, authorised by the responsible clinician, received optimal treatment from a comprehensive range of appropriate treatment choices following a pharmacist-led clinical review by the third party pharmacist.

Bayer was very disappointed that the email referred to Xarelto in the context of the ASC service. This was inconsistent with the legitimate objectives and approved name of this therapy review service. The third party service provider had acknowledged that this was an error made in this instance, and not a name for the service recognised or used within the third party.

Bayer submitted that its approved clinical protocol for the ASC service (ASC2 clinical protocol (March 2017), the brief to the third party pharmacists (ASC 2 brief (November 2016)) and the service contract between the third party and Bayer plc (May 2012) provided clear evidence of Bayer's intentions for the provision of the service and in expectations of the third party in delivering this service. For instance, the brief to pharmacists made it clear that they were to know about the current relevant guidelines for the management of AF and all relevant SPCs for available anticoagulants used in the prevention of stroke in AF. Neither the third party service provider nor its pharmacists were instructed or rewarded to prioritise Bayer medicine(s) or any other particular medicine when delivering the service. The structure of the service and its implementation, as shown from the documentation, did not link or associate the name of the service (anticoagulation support clinic) or its implementation to a specific Bayer product(s) as

alleged. Bayer also noted that the selection of eligible patients was not predicated on the use of a particular medicine; the authorising clinician or healthcare organisation (HCO) responsible for the patients were in full control of the entire review process, including any prescribing decision or intervention.

Bayer stated that it did not support the provision of this service as an inducement to prescribe, supply, administer, recommend or sell a particular medicine. Documentation, instructions and declarations of sponsorship on relevant materials were evidence of both the legitimacy and appropriateness of the service and its transparency, in relation to this project. Bayer had also not encouraged a link between the ASC service and Bayer medicine(s) and therefore it submitted that it had not breached Clauses 19.2 or 12.1 and thus had similarly not breached Clause 9.1 or 2.

Bayer noted that the complainants alleged that the named third party service provider had already submitted a proposal for a new therapy review to support coronary artery disease/peripheral artery disease (CAD/PAD) which linked the proposed service to Bayer's product. Bayer submitted that although it had received a proposal form from the third party in relation to supporting the NHS in this disease area, all discussions and compliance and legal reviews were at early stages; no draft documentation was in existence and no agreements were in place between Bayer and the third party. Bayer submitted therefore that no CAD/PAD therapy review service funded by Bayer was established and any communications from the third party should therefore not be perceived as activities conducted on behalf of Bayer, in relation to a CAD/PAD therapy review service. Bayer submitted that the allegation of CAD/PAD therapy review service linked to sponsor company product had not been justified and denied a breach of Clauses 19.2, 12.1, 9.1 and 2.

Bayer noted the complainant's allegation that it was not Code compliant for the third party service provider to email pharmacists about integrating client product/therapy prioritisation into the third party's internal resource and schedules. If, as interpreted by the complainants, such statement implied a link to Bayer's product in connection with the implementation of the ASC service, then Bayer would unreservedly disapprove of such link. The design and implementation of the service had always been as a legitimate therapy review service offering a range of treatment options. However, in the context of the opening and unredacted paragraphs of the email , Bayer questioned whether such statement was simply a recognition of the business reality of integrating different services into working schedules, that clinical training requirements were aligned to the therapy review services being implemented, and clinical staff had up-to-date knowledge on the latest treatment options and guidelines. In respect of the ASC service, the clinical protocol and other relevant materials, clearly reflected the legitimacy of the service and did not encourage or suggest prioritisation of a Bayer product(s) or any other particular medicine whilst delivering the service. Bayer supported the service unconditionally, had not encouraged the third party or its pharmacists to link or prioritise Bayer product(s) with the therapy review service and therefore it was not in breach of Clauses 19.2, 12.1, 9.1 and 2.

Bayer stated that according to the service contract between the third party and Bayer (May 2012), the third party was obligated to carry out services with all reasonable skill and care, and in full compliance of relevant established current professional standards and within the code of ethics set down by the General Pharmaceutical Council (GPhC), the Code and all other applicable codes of practice and regulations.

The ASC service was implemented only by registered pharmacists who were bound by their professional code of conduct. The third party ensured that the pharmacists who implemented the ASC service completed the National Centre for Anticoagulation Training (NCAT). The third party also had to provide product training on all available product options relevant to the therapy review area, including contraindications and interactions. This ensured that the service provided was in accordance with the Code, that the pharmacists could perform the service independently of Bayer and that the third party provided correct advice to the responsible prescribers. Bayer confirmed that the third party upheld the Code obligation as stipulated in the service contract, and requested that the third party provide confirmation that timely provision (and completion) of up-to-date Code training with their pharmacists and other relevant personnel had occurred. Bayer provided documented evidence of its due diligence in requesting and confirming the third party upheld its Code obligation.

Transparency was an important means of building and maintaining confidence in the pharmaceutical industry and Bayer stated that it publicly disclosed the transfer of value associated with this service accordingly on the ABPI portal. Bayer also consistently declared its involvement with the service on relevant materials associated with the delivery of this service. This included materials such as the patient consent form, the clinical protocol and the brief to the third party pharmacists.

As part of the therapy review process for inviting eligible patients for review, under the authority of the responsible clinician/HCO, the third party pharmacists had to introduce themselves to patients and declare Bayer's involvement with the service before requesting their consent for a review. This ensured that patients knew from the outset that the service was sponsored by a pharmaceutical company and were not otherwise misled.

As documented in the clinical protocol for this service (March 2017), the provision of the service was unconditional and Bayer did not continue to support the provision of this service to the NHS based on any achievements. Bayer also did not align the provision of the service with the prescribing, supply, administration, recommendation or sale of a particular medicine.

The named third party service provider provided Bayer with the number of days of service rendered (for invoicing purposes), the dates and locations of ASC therapy reviews booked by the third party (in order to ensure that representatives did not promote in surgeries where an ASC review service was actively taking place). Bayer also requested and captured data on the cumulative number of patients that had enrolled in the ASC therapy review service on a quarterly basis as part of its internal duty to monitor that the service was being delivered and also for pharmacovigilance purposes.

Bayer did not request or receive from the third party details of any assessments, independent recommendations or authorised interventions provided by their pharmacists when delivering this service, nor did the company monitor the number or proportion of patients prescribed a Bayer medicine or any other medicine as a result of the reviews. Bayer therefore, did not know the proportion of patients changed to a Bayer product as a result of the reviews.

Bayer submitted that coaching pharmacists on 'client value' was not a reference term that it was aware of or used and the company was not privy to these terms or what was implied by them.

Although Bayer believed that an error was made by the third party in reference to the ASC service (which Bayer in no way approved of or endorsed), Bayer asserted that the ASC review

service had been executed in a Code compliant manner and implemented by professional pharmacists in compliance with the Code and their professional obligations.

Bayer stated, in conclusion that it was committed to providing legitimate and compliant therapy review services to meet a genuine clinical need to improve patient outcomes and its documentation and instructions to the third party on the provision of this service reflected the company's legitimate intentions. Bayer did not encourage a link between the therapy review service and its medicine(s) and therefore it denied any breach of Clauses 19.2, 12.1, 9.1 and 2 of the Code.

In a subsequent response Bayer confirmed that the complainants were correct when they stated that Bayer was an existing long-standing client of the third party which had been providing therapy review services, on behalf of Bayer, since 2012. Bayer had, over the course of working with the named third party service provider, funded and launched two therapy review services, to support the NHS and patients with atrial fibrillation (AF) at risk of stroke. The two AF-led therapy review services were a Stroke Prevention in Atrial Fibrillation (SPAF1) therapy review service (launched in 2012) and an Anticoagulation Support Clinic (ASC2) (launched in 2015).

ASC2 was the only active AF related therapy review service between Bayer and the third party. The SPAF1 was no longer live or funded by Bayer and the decision to withdraw the service was made in May 2018, with the final service taking place in September 2018.

The SPAF1 service was initially designed to offer requesting GP practices with a pharmacist-led clinical assessment of patient's medical notes via the GP clinical system or other primary care case notes within the practice. Based on the medical notes assessment, the pharmacists were permitted to propose a review by the practice or a clinical intervention, both of which were at the discretion of the authorising GP practice to address or implement.

ASC2 was designed to provide a service comparable to that of SPAF1, but with the addition of helping the requesting practises optimise identified patients with AF at risk of stroke and on oral anticoagulants (OAC) via a pharmacist-led clinic also. An important distinction between SPAF1 and ASC2 was that in the latter, pharmacists were permitted to conduct patient-facing clinical assessments, upon request from the authorising practice. SPAF1 was fundamentally a review service providing clinical recommendation to authorising GPs, based on a review of the patients' case notes alone.

Both review services were conducted in accordance with the GP practice intervention specification and the third party pharmacists were instructed to work within the confines of the protocol and the clinical stipulations and at the discretion of the authorising GP. However, many healthcare practices were unable to review proposals from the SPAF1 service made by a third party pharmacist, most likely due to limited clinical capacity and resources within the practices. This was particularly concerning regarding AF patients at risk of stroke on no anti-coagulation, identified by the pharmacist in SPAF1, but not subsequently reviewed by the GP. ASC2 was designed to address this.

By May 2018, Bayer decided to withdraw SPAF1 service and ceased to offer this service to practices nationally. However, SPAF1 reviews booked by the pharmacists, prior to when this decision was made, were honoured with the last clinic booking made up until September 2018. By 27 September 2018, SPAF1 was terminated and funding was withdrawn completely for this

service. ASC2 then became the only active AF-related therapy review service funded by Bayer and delivered by the third party and remained so.

Bayer submitted that 'Atrial Fibrillation Review' had not been an umbrella term used by Bayer to describe the SPAF1, ASC2 services or both. At the point when the complaint was made on 21 April 2019, ASC2 was the only active third party delivered therapy review service funded by Bayer. Further the email in question referred to Bayer's commitment to AF review for 2018 with a focus on ASC2 clinics. SPAF1 was a service, already winding down in May 2018 and finally terminated in September 2018. Therefore, Bayer provided details in its original response regarding the active ASC2 therapy review service specifically. Other historic terms used by Bayer to refer to these Atrial Fibrillation-related therapy review services included 'AF programme' for the SPAF1 service and 'Anticoagulation Clinic service' for ASC2.

The terms listed above encapsulated all terms used in documentation between Bayer and the third party to describe both the SPAF1 and ASC2 service. 'Anticoagulation Support Clinic' referred to ACS2 specifically and was not an umbrella term. Bayer assured the PMCPA that the therapy review services listed above encapsulated all the AF-related therapy review services between Bayer and the third party and its disclosure of Bayer funded therapy review services delivered by the third party was complete in that regard.

Bayer refuted the further allegations by the complainant that Bayer was responsible for the conduct of the third party in relation to a proposal of a CAD/PAD service.

The complainants' allegation that Bayer and the third party were 'in the stages of forming a service' did not make sense. Bayer stated that it only ever received a proposal from the third party in relation to supporting the NHS and patients in this disease area. There was not and had never been a contract for services with the third party to commence any work on a CAD/PAD service; no concept document or service documentation had ever been drafted or approved.

Bayer agreed with the case preparation manager that there was no *prima facie* case for Bayer to answer on the allegation regarding a CAD/PAD service. Bayer submitted that the complainants had not provided any evidence to establish that a proposed service, the terms and details of which had not been agreed, should fall within the scope of the Code for a case complaint.

Bayer's position on this allegation was that no CAD/PAD therapy review service funded by Bayer was agreed or established. Any communications from the third party should therefore not be perceived as activities conducted on behalf of Bayer, in relation to a CAD/PAD therapy review service.

The allegation of CAD/PAD therapy review service linked to sponsor company product had not been justified and therefore Bayer denied a breach of Clauses 19.2, 12.1, 9.1 and 2 of the Code.

In conclusion, Bayer submitted that it was committed to providing legitimate and compliant therapy review services to meet genuine clinical need to improve patient outcomes and its documentation and instructions to the third party on the provision of this service reflected its legitimate intentions. Bayer in no way encouraged a link between therapy review services and

prescribing of its product(s) and therefore stated that it was not in breach of the clauses alleged in the complainants' letter.

In response to a request for further information, Bayer submitted that the third party provided it with a cumulative number of patients that had enrolled in the ASC 2 therapy review service (which had also been referred to as 'Anticoagulation Support Clinic', ASC2 or 'ASC') on a quarterly basis as part of Bayer's internal duty to monitor that the service was being delivered and for pharmacovigilance purposes.

In line with the requirement, a member of the third party medical or compliance team sent quarterly updates via email to the Bayer UK medical team which included the number of consented patients that attended a face to face appointment and were subsequently seen by a pharmacist as part of the service provision.

Bayer submitted that this information, provided by the third party, was then recorded internally at Bayer as part of its internal safety reporting requirement for any therapy review service supported by Bayer that involved direct interaction with patients and as part of its duty to track that the service was being delivered.

Bayer provided the quarterly update emails from the third party service provider team and a tabulated summary of the number of patients that had consented and been seen by a pharmacist as part of the service provision that had been provided to the UK medical team at Bayer by the third party since 2017 to date.

Bayer submitted that as stated in its initial response, the third party provided Bayer with the number of days of service rendered (for invoicing purposes) and the dates and locations of therapy reviews booked by the third party pharmacists in order to ensure that representatives did not conduct promotional activities in surgeries where a review service was taking place.

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 were 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 by 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 Bayer] products'. It was extremely concerning that in places the email linked the service to particular products or only offered the service in practices where the formulary did not preclude the company's product. This and the reminder regarding developing the business including the phrase 'integrate client product/therapy priorities' could link company products to a therapy review service. Even where a particular product was not mentioned by name it was extremely likely that the company's product would be linked to the relevant therapy review, as understandably many of the recipients might see integrating client product/therapy priorities as increased prescribing of the company's medicines. The reputational gain from supporting implementation of NICE Guidelines and other relevant guidelines and the improvements in patient care might not be seen by recipients of the email as delivering client value or integrating product/therapy priorities. The important consideration for the Panel was the effect and influence of the email in question in relation to all the other arrangements for each therapy review.

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

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

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

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

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

The Panel noted the complainant's allegation that the third party service provider coached its pharmacists on client value which was a guise for return on investment and that this was historically done verbally. In addition conversations pharmaceutical company staff and 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/3188/4/19

The Panel noted the complainants' view that Bayer had two therapy review services under the umbrella term 'atrial fibrillation review' referred to within the email in question.

The Panel noted Bayer's submission that it had, over the course of working with the named third party service provider, funded and launched two therapy review services, delivered by the named third party service provider, to support the NHS and patients with atrial fibrillation (AF) at risk of stroke. The AF therapy review services were firstly a Stroke Prevention in Atrial Fibrillation (SPAF1) therapy review service (launched in 2012) and secondly an Anticoagulation Support Clinic (ASC2) (launched in 2015). The Panel noted Bayer's submission that 'atrial fibrillation review' was not a term used by Bayer to describe either SPAF-1 or ASC2 services and that 'Anticoagulation support clinic' referred to ACS2 specifically.

The Panel noted that the third party email which was the subject of the complaint referred to '… 2' clinics. The Panel further noted that Bayer decided to withdraw SPAF1 in May 2018, prior to the date of the email in question (14 August 2018). However, SPAF1 reviews booked by the pharmacists, prior to when this decision was made, were honoured with the last clinic booking made up until September 2018. By 27 September 2018, SPAF1 was terminated and funding withdrawn. ASC2 then became the only active AF-related therapy review service funded by Bayer and delivered by the third party and remained so. Noting its comments above, the Panel considered that the complainants had not discharged their burden of proof that the email in question referred to SPAF1. In the Panel's view, the reference to atrial fibrillation review in the email was in relation to ASC2 only. The Panel therefore decided it would not consider SPAF1.

The Panel noted Bayer's disappointment that the email at issue referred to Xarelto in the context of the ASC service. Bayer submitted that an error was made by the third party in this regard and the reference to Xarelto was inconsistent with the legitimate objectives and approved name of this therapy review service. Further, the third party had acknowledged that it had made an error in this instance, and it was not a name for the service recognised or used within the third party.

The Panel noted Bayer's submission that the ASC service aimed to improve patient outcomes in conditions associated with anticoagulation use such as stroke prevention in atrial fibrillation (AF). It aimed to ensure patients, authorised by the responsible clinician, received optimal treatment from a comprehensive range of appropriate treatment choices following a pharmacist-led clinical review by a third party pharmacist. According to ASC2 clinical protocol (March 2017) the service aimed to achieve its objective by, *inter alia*, ensuring that the prescribing of non-VKA oral anticoagulants was appropriate for the patient on the basis of approved indications, patient suitability and avoiding interruption of therapeutic anticoagulation during the transition.

The Panel noted Bayer's submission that the complaint had fallen within the period of recertification of relevant materials. Therefore it had provided copies of both previous and current versions of relevant materials.

The Panel noted that in its response Bayer referred to its approved clinical protocol for the ASC service (ASC2 clinical protocol (March 2017)), the brief to the pharmacists (ASC2 brief to the pharmacists (November 2016)) and the service contract between the third party and Bayer plc (May 2012). These were the documents reviewed by the Panel as in its view they were relevant

at the time the email in question was sent (August 2018). The Panel noted Bayer's submission that the original brief to pharmacists (certified April 2017) was recertified (March 2019) before its recertification due date in April 2019. However, several additional materials which were provided as appendices in the original brief and due for recertification had, for this latest iteration, been separated out and certified as individual items between March and May 2019.

The Panel noted that the service aims and objective and the process algorithm in the 2017 and 2019 clinical protocol documents appeared to have some differences. The Panel noted that according to Bayer, there had been no changes to the core conduct of the ASC service and key changes between previous and current versions included: update to the declaration of confidentiality section in the clinical protocol; amendments to ensure consistency in the wording across all documents regarding Bayer's involvement with the ASC service; consolidation of previous patient invite letter templates to two templates and creation of a template to invite patients who had not responded to an initial invite.

The Panel noted that the Bayer salesforce briefing document (July 2017) was titled Bayer Salesforce Briefing Document for SPAF1 therapy review service and appeared to focus on this service. The Panel noted Bayer's submission that the SPAF1 service was fundamentally a review service providing clinical recommendation to authorising GPs, based on a review of the patients' case notes alone. ASC2 was designed to provide a service comparable to that of SPAF1, but with the addition of helping the requesting practices optimise identified patients with AF at risk of stroke and on oral anticoagulants via a pharmacist-led clinic. The salesforce briefing document (July 2017) briefly described how a SPAF1 service could link into an ASC2 service. It appeared that of the three patient cohorts following step 1 of SPAF, all three could continue with either SPAF1 or enter ASC2 clinic support. The Panel noted that the ASC2 service was launched in 2015 and therefore would have been active when this salesforce briefing was created. The Panel noted that the only salesforce briefing for ACS provided by Bayer was dated May 2019. The Panel was concerned that there did not appear to be any specific salesforce briefing in place with regard to the ASC2 therapy review service at the time the email in question was sent.

Both salesforce briefing documents stated that this medical educational good or service (MEGS) was proactively offered to practices based on a medical need. The July 2017 salesforce briefing document stated that a certified list of practices with highest clinical need was produced and provided by Bayer using a ratified tool determined by a composite list of high risk patients not currently anticoagulated and sub-optimally controlled on warfarin. The list was derived from nationally available datasets such as quality outcome frameworks (QoF). There was no similar information within the ASC 2019 salesforce briefing document provided. The July 2017 salesforce briefing document also stated that Bayer salesforce must only use the service introduction document for the sign up of this service.

The Panel noted Bayer's submission that the clinical protocol (March 2017) instructed the third party and its pharmacists on how to implement the service to a compliant standard as approved by Bayer. Selection of patient cohorts eligible for the service was achieved by either the authorising clinician/healthcare organisation (HCO) or generated by the third party pharmacist based on the approved cohort criteria details. According to the March 2017 Clinical protocol the inclusion criteria included the following four patient cohorts:

- Antiplatelet monotherapy or no current therapy for stroke prevention in AF
- Clinical issues with current oral anticoagulant for stroke prevention in AF

- Clinical issues with current oral anticoagulant for prevention of recurrent VTE
- Currently taking low molecular weight heparin (LMWH) therapy for long term prevention of VTE.

Patients were identified that were suitable to transition to/initiate a non-VKA anticoagulant for stroke prevention in AF and prevention of recurrent VTE in at risk patients.

The Panel noted Bayer's submission that the selection of eligible patients was not predicated on the use of a particular medicine; the authorising clinician or healthcare organisation (HCO) responsible for the patients was in full control of the entire review process, including any prescribing decision or intervention.

The Panel noted Bayer's submission that neither the third party nor its pharmacists were instructed or rewarded to prioritise Bayer medicine(s) or any other particular medicine when delivering the service. The Panel further noted Bayer's submission that the structure of the service and its implementation, as shown from the documentation, did not link or associate the name of the service (anticoagulation support clinic) or its implementation to a specific Bayer product as alleged.

The Panel noted Bayer's submission that prior to a therapy review, the authorising clinician pre-specified, to the third party pharmacist, his/her preferred anticoagulant for stroke prevention in atrial fibrillation and this specification directed the pharmacist's review and recommendations in relation to therapy interventions. The Panel noted from the clinical protocol (March 2017) that prior to the review the authorising clinician had to complete a form giving the preferred non VKA anticoagulant for stroke prevention in atrial fibrillation and similarly for the preferred non VKA anticoagulant for recurrent prevention of venous thromboembolism. The Panel noted that the form allowed for a first and second option to be stated. The Panel further noted that there appeared to be four DOACs available (Eliquis, Pradaxa, Lixiana and Xarelto).

The clinical protocol (March 2017) stated that no patient would be initiated onto a medication beyond the scope of the summary of product characteristics (SPC) unless authorised by the prescriber.

The Panel noted that the briefing to the third party pharmacists (November 2016) stated that they were to know about the current relevant guidelines for the management of AF and VTE and all relevant SPCs for available anticoagulants used in the prevention of stroke in AF and for the recurrent prevention of VTE. According to Bayer the third party service provider ensured that the pharmacists who implemented the ASC service completed the National Centre for Anticoagulation Training (NCAT) at Birmingham or Warwick Universities. The third party also had to provide product training on all available product options relevant to the therapy review area, including contraindications and interactions.

The Panel noted Bayer's submission that the third party pharmacists had to introduce themselves to patients and declare Bayer's involvement with the service before requesting their consent for a review and that declarations of sponsorship were made on relevant materials in relation to this project.

The Panel noted that the brief to the third party Pharmacists (November 2016) included a comparison of drug interactions with each of four non-VKA oral anticoagulants (Eliquis, Pradaxa, Edoxaban, and Xarelto). This was not provided with the replacement brief (March

2019). The Panel was not clear why this document was included in the papers for the service. The comparison table might be seen as suggesting one product over others based on interactions. Out of potential drug interactions listed, the table appeared to imply that in relation to significant interactions Pradaxa (dabigatran) had the most combinations classified as contraindicated or not recommended and Lixiana (edoxaban) the fewest in this regard.

The Panel noted that both the clinical protocol and ASC 2 pharmacist briefing stated that anonymous statistical data would be provided to Bayer so that it could monitor and confirm that the desired service to medicine was or had been delivered. This data appeared to be the number of patients that had consented and had been seen by a pharmacist as part of the service provision. Following a request for information Bayer provided various redacted emails in relation to the number of patients who participated.

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 named third party service provider linked its therapy review services to the products of the sponsoring pharmaceutical company; historically the third party had done it verbally, being careful not to put anything in writing.

Whilst the Panel had concerns about how the email portrayed the named third party service provider therapy services and the link of the ASC service supported by Bayer to its product Xarelto, it nonetheless noted that the complainants bore the burden of proof. In the Panel's view, it was not unreasonable that some if not all of the third party pharmacists would associate the Bayer therapy review with Bayer products and in the particular circumstances of this case would link the Bayer therapy review to Xarelto based on the email at issue. However, taking into account all of the circumstances including the Panel's view that Bayer's written arrangements for the service did not appear to amount to a switch to Bayer medicines, the Panel did not consider that the complainants had established, on the balance of probabilities, that the arrangements for the ACS therapy review supported by Bayer were such that they failed to meet the requirements of Clause 19.2 of the 2016 Code. 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.

In the Panel's view, Bayer had been let down by its third party agency in that the email at issued implied that the review was linked to Bayer's product Xarelto.

The Panel noted that Bayer appeared to have in place the appropriate documentation that did not link the therapy service to its product. The Panel noted, however, that it was a well-established principle that a company was responsible for the acts or omissions of its agents or third parties. If this were not the case companies would be able to rely on such acts or omissions as a means of circumventing the requirements of the Code. In the Panel's view, the email at issue was instructing the third party pharmacists in relation to a therapy review service for which Bayer was responsible and linking the service to Bayer's product Xarelto. The Panel considered that high standards had not been maintained in this regard and a breach of Clause 9.1 of the 2016 Code was ruled.

The Panel did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and reserved for such use.

Regarding the CAD/PAD service, the Panel noted Bayer's submission that it only ever received a proposal from the named third party service provider in relation to supporting the NHS and patients in this disease area. There was not and had never been a contract for services with the third party to commence any work on a CAD/PAD service; according to Bayer, no concept document or service documentation had ever been drafted or approved.

Whilst the Panel had concerns about the email at issue in this regard, there was no evidence before it that Bayer had commissioned a therapy review service with regard to CAD/PAD or linked it to rivaroxaban and no breach of Clauses 19.2 and 12.1 of the 2016 Code were ruled.

The Panel subsequently ruled no breach of Clauses 9.1 and 2.

* * * * *

During the consideration of this case the Panel was concerned to note that whilst the original brief to the third party pharmacists (dated November 2016 and certified April 2017) was successfully recertified before its recertification due date in April 2019, several additional materials which were contained as appendices in the original brief and due for recertification had been separated out and certified as individual items between March and May 2019. The recertification dates for some materials fell beyond the April 2019 due date. The Panel noted Bayer's acknowledgment of a lapse in recertifying certain relevant materials and that it would put in place an appropriate corrective action, preventive action plan to ensure that this issue did not happen again. In the Panel's view, a robust certification procedure underpinned self-regulation and its asked that Bayer be advised of its concerns.

APPEAL BY THE COMPLAINANTS

The complainants appealed the ruling of no breach of Clause 2 bringing discredit upon, or reducing confidence in, the pharmaceutical Industry.

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

> Pharmaceutical companies investing in therapy review services were very likely to have commercial interests in this area.
>
> Materials whether they be from the company or third party should not link a therapy review to a particular product.
>
> In the Panel's view, the email in question 14.08.18 might be seen by the third party pharmacists as instructions on how the therapy reviews should be conducted.
>
> In the Panel's view, Bayer had been let down by the third party in that the email at issue implied that the review was linked to Bayer's product Xarelto.
>
> In the Panel's view, the email at issue was instructing the third party pharmacists in relation to a therapy review service for which Bayer was responsible and linking the service to Bayer's product Xarelto.

> In the Panel's view, the overall impression of the email was such that 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.
>
> 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 within the email was particularly concerning when the third party 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. These comments were not conducive to therapy review service which was maintaining high standards of Code compliance.

PAD/CAD Review: Appeal Clause 2

The complainants acknowledged Bayer's submission that it had only received a proposal from the named third party service provider. The email in question, 14 August 2018, stated that 'their strategic focus is to push for a license extension of Rivaroxaban into CAD and PAD…we have already submitted a proposal for a new review to support these new indications are hopeful of adding this second service into the [the named third party service provider] portfolio over the coming months'. Bayer submitted that no CAD/PAD service was established, however, the email from the named third party service provider suggested the service would be available over the coming months.

The complainants alleged that either the senior employee of the third party was attempting to paint an optimistic outlook for remaining staff (albeit misleading) on the back of mass resignations, and the service was in fact at proposal stage only, or that the service was considerably further along the development path than the Panel was led to believe.

The complainants alleged that Bayer had still engaged with the third party around a CAD/PAD service and the third party communication sent to the entire clinical team suggested a service in this area was likely and made a clear undisputable link to Bayer's product Rivaroxaban/Xarelto.

The complainants stated that there must be accountability in this case. It must not be possible for a pharmaceutical company to engage, on any level, with an 'independent' 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 2 was entirely appropriate in this case, which would also serve as a warning to other pharmaceutical companies and service providers wishing to engage in this manner, that this kind of behaviour would not be tolerated. The email highlighted that the named third party service provider had a very clear intent where it had proposed a new review to coincide with the licence extension of Rivaroxaban. The complainants urged the Appeal Board to consider how the NHS and patients would view the pharmaceutical Industry when these facts were published.

The complainants disagreed with the original ruling around CAD/PAD and maintained that, on the balance of probabilities, the original complaint email (14 August 2018) 'WAS' enough evidence, to demonstrate that Bayer had brought discredit upon, and reduced confidence in, the pharmaceutical Industry (Clause 2), through their third party acting on its behalf.

Disputed SPAF1 Service

Timing of withdrawal

The complainants alleged that Bayer claimed it had decided to withdraw the SPAF1 service by May 2018, however, this was only a decision to withdraw and did not constitute termination of the service. Clinics were still being delivered until September 2018, to honour bookings made prior to May 2018. Bayer stated the SPAF1 service was not terminated until 27 September 2018. If the service was still being delivered and was not terminated until 27 September 2018, then it was still a live service on 14 August 2018 when the email at question was written. The complainants, therefore, appealed that Panel's ruling and maintained they should include the SPAF1 for the complaint.

Term 'AF review'

The complainants noted that from the email dated 14 August 2018: Bayer was committed to the Xarelto (Rivaroxaban) AF review for 2018 with a focus on ASC-2 clinics. The email referred to the term 'AF review' and did not specify which one. It merely said there was a 'focus' on ASC2 clinics, which did not exclude SPAF1. The complainants disagreed with the Panel's comments that the email in question was in relation to ASC2 only and that the complainants had not discharged the burden of proof. Bayer had clearly stated that their SPAF 1 review was not terminated until 27 September 2018 and was being delivered up until September 2018. There were, therefore, two 'live' services which involved reviewing AF patients at the time of the email in question, 14 August 2018. Therefore, the complainants were confident with the facts laid before them and maintained that the Panel should consider SPAF1 for the complaint.

SPAF-1/ASC-2

The complainants noted that in the Panel's view, the email at issue was instructing pharmacists in relation to a therapy review service for which Bayer was responsible and linking the service to Bayer's product Xarelto. The complainants agreed with the Panel that high standards had not been maintained, however, maintained that a breach of such seriousness should warrant a breach of Clause 2 ruling. There was no doubt in the view of the complainants, that the email in question and the link to Rivaroxaban/Xarelto had brought discredit upon, and reduced confidence in, the pharmaceutical Industry.

The complainants alleged that thousands of patients had been reviewed by the third party under the financial sponsorship of Bayer and a senior employee had been exposed openly linking Xarelto to the AF service in a company-wide email. There were many NHS organisations, health professionals, patients and the wider healthcare sector who would, without doubt, now question the integrity of the pharmaceutical industry and their involvement in sponsored therapy review services. NHS organisations and clinicians who had previously had Bayer-sponsored Atrial Fibrillation services provided by the third party service provider and who signed up with

the reassurance that the services were Code compliant would, without doubt, now question the integrity of the reviews which were conducted.

The complainants alleged that the original complaint email (14 August 2018) '**IS**' sufficient evidence, on the balance of probabilities, to demonstrate that Bayer had failed to maintain high standards (Clause 9.1) and brought discredit upon, and reduced confidence in, the pharmaceutical Industry (Clause 2) through their third party acting on their behalf. The complainants disagreed with the original ruling that the circumstances did not warrant a breach of Clause 2 ruling and would like to stress the seriousness of the breach and the potential ramifications for the NHS and the pharmaceutical industry.

The complainants stated that although Bayer submitted that an error was made by the third party service provider in reference to the ASC service (which Bayer in no way approved or endorsed), Bayer asserted that the ASC review had been executed in a Code compliant manner and implemented by professional pharmacists in compliance with the Code and their professional obligations. The complainants did not understand the logic of Bayer's claim that the service could be executed in a Code compliant manner when the email clearly showed the senior employee of the third party referring to the service as 'a Rivaroxaban/Xarelto review' to the company. Even the Panel had said that in its view, 'the email at issue was instructing the third party pharmacists in relation to a therapy review service for which Bayer was responsible and linking the service to Bayer's product Xarelto'. Based on this, the complainants alleged that Bayer could not possibly claim that the reviews had been conducted in a Code compliant manner.

Remorse

The complainants noted that Bayer was 'very disappointed' that the email from the third party service provider referred to Xarelto and that there was an 'acknowledgement' of an 'error' from the third party. The complainants alleged that these were rather soft terms used which underplayed the seriousness of what, in fact, occurred: A gross management failing exposing the true culture and inherent product bias at the third party towards the sponsoring company's product. The complainants disputed the claim from the third party that it was not a name for the service recognised or used within that organisation. <u>It undisputedly was</u> and the email evidence (14 August 2018) which was sent to the company was as clear as day. If it was not a term recognised or used within the third party service provider, then the complainants asked the Appeal Board to question why it was written in the email. The complainants asked the Appeal Board to document this futile attempt to palliate the seriousness of the term 'used'.

The complainants alleged that there was no suggestion of remorse or regret from the third party service provider or Bayer. One would expect the email dated 14 August 2018 to be retracted and combined with an apology to all recipients. After all, in the Panel's view, the email at issue was instructing the third party pharmacists, in relation to a therapy review service for which Bayer was responsible and linking the service to Bayer's product Xarelto.

Other issues highlighted by the Panel

The complainants alleged that at the time the complaint was submitted, serious failings had been exposed by the Panel such as expired certification of Bayer materials being used by the third party pharmacists.

The complainants were confident that Bayer and the third party were only aware of this serious failing because of this complaint. The complainants alleged that the service was being conducted with pharmacists using expired versions of documents putting clinicians, their patients and third party pharmacists at risk, regardless of what subsequent changes were made.

Other serious failings highlighted by the Panel included:

- No salesforce briefing in place for ASC 2 at the time of the email in question.
- ASC 2019 Salesforce briefing document did not contain reference to a certified list of practices with highest clinical need whereas the July 2017 briefing document did.
- The pharmacist brief 2016 included a comparison of drug interactions which was not provided with the replacement brief March 2019.

The complainants were already aware of these serious failings and had already scheduled to challenge Bayer once this complaint regarding the email dated 14 August 2018 was complete. The complainants were unsure if the Panel would address this now. If it did, naturally due to the seriousness of these failings around materials, the complainants alleged a breach of Clause 2 as without any doubt, Bayer had brought discredit upon, and reduced confidence in, the pharmaceutical Industry.

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

COMMENTS FROM BAYER

PAD/CAD Review: Appeal of Clause 2

Bayer stated that as described in its initial response to this complaint, it was provided with a proposal in relation to a potential CAD/PAD therapy review service by the third party service provider, and this proposal was, at the time of receipt of the complaint (9 May 2019), in early stages of legal and compliance review. Bayer had strict policies and procedures under which all proposals for services underwent a thorough compliance and legal review before approval, implementation and launch. No such reviews had been completed, no concept document or service documentation drafted or approved, and no agreement entered into with the third party service provider for such service. No CAD/PAD therapy review service had or had since been launched. The email dated 14 August 2018 indicated that the service provider was ‘hopeful’ of adding the service, again indicating that no service had been agreed.

Bayer submitted that it could not be responsible for the conduct of the third party in relation to a proposal of a CAD/PAD service where the proposal had not been fully reviewed or approved and no service contract between Bayer and the third party was in place.

Bayer’s position on this allegation remained the same. No CAD/PAD therapy review service funded by Bayer was agreed or established. Any communications from the third party should therefore not be perceived as activities conducted on behalf of Bayer, in relation to a CAD/PAD therapy review service.

The allegation of CAD/PAD therapy review service linked to sponsor company product had not been justified and therefore Bayer submitted that it was not in breach of the Code and specifically, not in breach of Clause 2 of the Code.

Disputed SPAF1 Service

Timing of withdrawal and Term 'AF review'

Bayer disagreed with the complainants' position that the Panel's ruling should include the SPAF1 for the complaint and disagreed that the term 'AF review' should include SPAF1.

As Bayer had explained in its previous response, a decision to withdraw SPAF1 was made in May 2018. Only SPAF1 therapy reviews already committed to at that date were honoured. As such, and at the time of the email in August 2018, there was no active engagement in relation to the availability of SPAF1 after May 2018.

Further, the redacted email referred to Bayer's commitment to AF review for 2018 with a focus on ASC2 clinics.

Bayer agreed with the Panel's decision that the reference of atrial fibrillation review in the email was in relation to ASC2 only. As such, no unnecessary information relating to SPAF1 had been provided. Brief details were, however, provided with Bayer's initial response.

SPAF-1/ASC-2

Bayer disagreed with the complainants that the original email (dated 14 August 2018) was sufficient evidence to claim that the ASC2 service had been conducted in a way that brought discredit upon, and reduced confidence in, the pharmaceutical Industry.

As set out in Bayer's initial response to the complaint, and as acknowledged by the Panel in their decision, Bayer had in place appropriate documentation that did not link the therapy service to its product. Bayer submitted that it supported the service unconditionally and had not, at any time, encouraged, supported or approved any link to Bayer product. The Panel had clearly expressed its concerns with regard to the email and had ruled in their response (13 December 2019) that high standards had not been maintained in this regard, but did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2. Bayer agreed with this decision and ruling by the Panel.

Remorse

In Bayer's original response it submitted that it had stated that it was very disappointed with the reference to Bayer's product in the context of the ASC service in the email. In addition, the third party service provider had acknowledged that this was an error made in this instance.

Following on from the Panel's ruling that high standards had not been maintained in this regard, Bayer acknowledged and accepted the decision of the Panel in this case without appeal. Bayer had since provided assurance to the PMCPA that all possible steps would be taken to avoid such similar breaches of the Code from occurring in the future.

Bayer submitted that it took compliance seriously and strove to abide by the Code to operate in a responsible, ethical and professional manner.

Other issues highlighted by the Panel

Bayer submitted that these issues were not raised by the complainants in their original complaint and therefore were not subject to the ruling by the Panel or the Appeal Board in this case. However, Bayer had provided its brief comments on these points in order to reassure the Appeal Board of the seriousness with which it took its obligations in these matters.

As part of the Panel's decision in this case, the Panel had expressed its concerns about the lapse in re-certification of several additional materials for ASC2 but had also noted Bayer's acknowledgement of the lapse in re-certification and that Bayer would put in place corrective and preventive actions to ensure this did not happen again. Bayer submitted that its acknowledgement of the lapse in recertification, and assurance to put in place corrective and preventive actions to ensure it did not happen again, had addressed this issue.

Although the salesforce briefing referred to SPAF 1 only in the title page, it was important to note that this briefing document (July 2017) referred to ASC2 and the instructions provided to Bayer representatives in this version of the briefing were sufficient to inform them of their roles and conduct of the service. As such, Bayer submitted a salesforce briefing was in place that instructed Bayer's representatives regarding the ASC2 therapy review service.

Bayer submitted that the reference to the certified list of practices of highest clinical needs in the briefing to the Bayer representatives (July 2017) was not referred to in the subsequent replacement briefing (May 2019) because the list of qualifying practices at highest clinical need had the potential to continually evolve over time and that the instruction in the Bayer representative brief (March 2019), for this MEGS to be proactively offered to practices based on a medical need, would suffice.

Bayer submitted that the section of the third party pharmacist brief (November 2016) summarising the drug-drug interactions of the four direct oral anticoagulants (DOACs) was subsequently removed in the replacement brief (March 2019) because the list of drug-drug interactions for respective DOACs had the potential to change over time and the brief to pharmacists to have a detailed working knowledge of all relevant SPCs for the available anticoagulant therapies used in the prevention of stroke in atrial fibrillation and anticoagulant therapies for the recurrent prevention of VTE would suffice. Bayer neither submitted that the inclusion or removal of the drug-drug interactions section in the pharmacist briefing nor the inclusion or removal of a certified list of practices in Bayer representative briefing was inappropriate.

FINAL COMMENTS FROM THE COMPLAINANTS

The complainants referred to their original appeal comments with regard to the 'PAD/CAD review: Appeal Clause 2'. Bayer was named in an email (14 August 2018) from its 3rd party service provider where its medicine, rivaroxaban had been indisputably linked to its proposed therapy review service, PAD/CAD, and already established services in Atrial Fibrillation. The complainants understood Bayer's position was to defend at all costs however, they urged the Appeal Board to consider the wider picture and the whole relationship between Client (Bayer) and Service Provider. What was demonstrated with the PAD/CAD was a clear intent between

two parties who were well established in working together. The email highlighted that the third party had a very clear intent where it had proposed a new review to coincide with the license extension of rivaroxaban. The complainants urged the Appeal Board to consider how the NHS and patients would view the pharmaceutical Industry and their funding of pharmacist-led service providers when the case was published. The complainants referred to 'Dispute SPAF[1] Service Timing of withdrawal' in their original appeal comments where they alleged this had been addressed already. The complainants were confident Bayer was incorrect in its assertions and dates. The complainants referred to the term 'AF' Review from the email dated 14 August 2018: 'Bayer are committed to the Xarelto (Rivaroxaban) AF review for 2018 with a focus on [ASC…2] clinics'. The complainants challenged that if there was only one live 'AF review', then it did not follow logical sense to add in 'with a focus on [ASC-2] clinics'. It was clear to the complainants that here were 2 live 'AF Reviews' as per the dates supplied by them and that Bayer was making it clear that it had more of a focus on clinics as opposed to the non-clinic review. The email referred to the term 'AF review' and did not specify which one. It merely said there was a 'focus' on ASC2 clinics, which did not exclude SPAF1. Bayer had clearly stated that its SPAF1 review was not terminated until 27 September 2018 and was being delivered up until September 2018. There were, therefore, two 'live' services which involved reviewing AF patients at the time of the email in question, 14 August 2018. Therefore, the complainants were confident with the facts laid before them all and alleged that the Appeal Board should consider SPAF1 for the complaint.

The complainants referred to their original appeal comments with regard to 'Remorse' and alleged that Bayer had no choice but to accept the original ruling. The complainants alleged that there was simply no grounds for Bayer to appeal the explicit naming of its product rivaroxaban with its AF service, which was a clear breach of the Code and, in the complainants' opinion, had brought discredit upon, and reduced confidence in, the pharmaceutical Industry. Interestingly, Bayer stated that the third party service provider had 'acknowledged that this was an error'. The named job title at the third party was responsible and accountable for Code compliance within that organization. He/she had not retracted the email or issued any apology to this day. The third party pharmacists continued to believe that the AF Review was a 'Rivaroxaban review' to date.

The complainants urged the Appeal Board to consider the following:

'– The complaint related to the email in question (14.08.18) and to request that Bayer was not permitted to detract from it by bringing up other parts of the service for which the complaint did not relate to.
– The PMCPA's comments in relation to the Bayer reviews complaint were very strong (damning in the Board's opinion) and warranted Clause 2 breaches.
– The established principle under the Code that pharmaceutical companies were responsible for third parties acting on their behalf even if that third party acted outside the instructions from the pharmaceutical company.'

The complainants stated that they would like the Appeal Board to review the original decision as they alleged that although Bayer had been let down by the third party service provider, it was responsible for the actions of its third party. The summation made by the PMCPA on the Bayer complaint strongly indicated that it had brought discredit upon, and reduced confidence in, the pharmaceutical industry.

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 the Appeal Board's view it appeared that Bayer's documentation was not unreasonable in that it did not appear to link the therapy review service to Bayer's product. The Appeal Board agreed with the Panel in that it appeared that Bayer had been let down by its third party service provider, as the email at issue implied that the review was linked to Bayer's product Xarelto. The Panel noted that Bayer was nonetheless responsible for the email as it related to Bayer. The email at issue was instructing the third party service provider pharmacists in relation to therapy review services including that for which Bayer was responsible and linking a Bayer therapy review service to Bayer's product Xarelto. The Appeal Board noted the Panel's ruling of a breach of Clause 9.1 in this regard which Bayer had accepted.

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 Xarelto to the ongoing therapy review. The Appeal Board considered that the wording was, at the very least, unfortunate particularly as it was directed to individuals who might deliver the services. The Appeal Board noted the submission of the company representatives at the appeal that the company understood that the aim of the letter was to reassure certain staff at a time of change but considered that given the subject matter of the email it nonetheless had to comply with the Code. Whilst the Appeal Board was concerned about the email in question no evidence was provided to show that the email impacted on the delivery of the service. Taking into account all the circumstances the Appeal Board considered that the matter was adequately covered by the ruling of a breach of Clause 9.1 and did not consider that a ruling of a breach of Clause 2 of the Code was warranted. The Appeal Board consequently upheld the Panel's ruling of no breach of Clause 2 in relation to the therapy review services SPAF1 and ASC2. The appeal on this point was unsuccessful.

The Appeal Board noted Bayer's submission that there was not and had never been a contract with the third party service provider to commence any work on a CAD/PAD service; according to Bayer, no concept document or service documentation had ever been drafted or approved. Whilst the Appeal Board had concerns about the email at issue, there was no evidence before it that Bayer had commissioned such a therapy review service or linked a possible CAD/PAD service to rivaroxaban and the Appeal Board upheld the Panel's ruling of no breach of Clause 2. The appeal on this point was unsuccessful.

This case was one of a number of cases as follows; Case AUTH/3190/4/19 Takeda, Case AUTH/3191/4/19 Amgen, Case AUTH/3193/4/19 Novartis, Case AUTH/3194/4/19 GlaxoSmithKline, Case AUTH/3195/4/19 Chiesi and Case AUTH/3197/4/19 Ethypharm.

Complaint received **30 April 2019**

Case completed **14 October 2020**