CASE AUTH/2823/2/16

ANONYMOUS, CONTACTABLE v GRÜNENTHAL

Conduct of representatives

A contactable complainant who wished to remain anonymous complained about Grünenthal's practices including the pressure put on representatives to perform in a manner which risked bringing the industry into disrepute.

The complainant referred to a previous upheld complaint about Grünenthal's expected call rates and alleged that Grünenthal's defence in that case that representatives were not incentivised on achieving call rates was untrue. The complainant alleged that sales representatives' bonus payments were based on unethical call rate expectations.

At the start of each quarter representatives created cycle plans which listed target customers and how many times they would be seen that quarter. The complainant understood that even stating that Grünenthal would see each of those customers once each quarter was a breach of the Code which allowed three calls per year. The complainant stated that Grünenthal was not happy with one call per customer per quarter which led to some representatives stating that they would see particular health professionals more than eleven times in a four month period. This was compounded by the fact that even if a representative achieved in excess of their sales vs target, if they did not achieve a minimum of 90% of the cycle plan they would not receive any bonus payment. This led to both the falsifying of calls and some representatives reporting more than twenty calls on one single doctor in a three month period. All representatives, even new representatives making their first call, were told to record calls as 'requested return visit' on the customer relationship management (CRM) system.

The complainant explained that Grünenthal also ran a GP pain education programme (GP-PEP). Representatives were to ask health professionals to act as paid speakers for these meetings. However, unless the health professional had prescribed the relevant product (most often Palexia (tapentadol hydrochloride)) to a minimum number of patients, they were not permitted by the company to speak. The complainant alleged that company compliance was poorly monitored, some consultants had spoken at meetings without a contract in place and others had not been paid for services provided. Representatives were set a target number of meetings to hold per quarter. Again, although their bonus did not rely on this, it was listed as a key performance indicator and failure to achieve the target level of meetings each quarter resulted in a reduction, or in some cases, a complete removal of an annual pay rise.

The detailed response from Grünenthal is given below.

The Panel noted that the complainant had the burden of proving their complaint on the balance of probabilities. The complainant had not provided any material to support his/her allegations but had provided a detailed account of their concerns. Further the complainant had not given details of the dates regarding his/her allegations. The case preparation manager had informed Grünenthal that the case would be considered under the Code relevant to the time that activities took place and had asked for details and copies of materials etc for representatives in the past two years.

1 Activity targets for representatives

In the previous case, Case AUTH/2652/11/13, Grünenthal was ruled in breach of the Code on the narrow ground alleged because the email in question was not sufficiently clear about the differences between call rates and contact rates as referred to in the relevant supplementary information in the Code.

The Panel noted Grünenthal's submission in the case now before it, Case AUTH/2823/2/16, that activity targets were established as part of overall cycle plans. The Panel further noted Grünenthal's submission that 'activity' could take the form of a face-to-face (1:1) call with a specified individual, or contact established when the individual was a delegate at a meeting. Grünenthal did not set or incentivise expected call or contact rates, instead it was the general collective 'activity' that was monitored.

The cycle plans were created by each representative based on local knowledge of what was required to drive business and the total number of interactions planned per individual target customer was also established by the representative based on what they had the potential to achieve. This could be zero, 1, 2, 3 etc … interactions over the cycle period, including calls requested by a customer. Representatives were not driven by Grünenthal to plan a minimum number of interactions with any given health professional. The Panel noted Grünenthal's submission that the default activity against all customers when working on a draft cycle plan was '1'. Representatives were instructed to increase or decrease this number accordingly for individual health professionals in order to create their overall cycle plan. The acceptance of '0' and '1' was described in briefing material sent to representatives.

Once the provisional cycle plans were created they were reviewed and/or challenged by line managers based on reasonable potential to attain the plan proposed and adherence to compliance requirements.

The Panel noted Grünenthal's submission that achievement of an individual's cycle plan each year was always based on total actual volume of calls vs total target volume so no daily call rate was required or stipulated.

The Panel considered that Grünenthal's submission that no daily call rate was required was not wholly accurate. Representatives were given a minimum interaction capacity per day and their provisional cycle plans were reviewed/challenged by line managers then validated. An email from a commercial director to the sales force made it clear that a key performance indicator on the cycle plan data was the daily rate of work that the quarterly volume of contacts delivered. In the Panel's view, the number of expected daily interactions would include, over the cycle plan, calls on target customers and others.

The Panel noted that Grünenthal promotional teams were provided with a commercial standards document at the beginning of each year which clarified business expectations including instructions to plan activity in line with the requirements of the Code, in addition to reminders within other communications. The Commercial Directorate Standards 2015 and 2016 defined a call as a one to one event with a customer and a contact as being a call or a meeting event. The documents further stated that the CRM system recorded customer interactions which was an internal term defined as a face-to-face call or meeting with a customer and on the same slide stated 'Our anticipated activity rates take into account the PMCPA code of conduct [respective year] and each customer should not have more than 3 unsolicited calls per year. However it is assumed a significant proportion of this activity will be on customer request'. The slide concluded that other activity could take place outside of the target lists and cycle plan and detailed that Grünenthal was resourced to deliver a certain number of total customer contacts per day. The 2016 slide stated in addition that this activity should not compromise the target activity achievement. The Panel queried how and where this other activity taking place outside of the target lists and cycle plans would be recorded. The Panel also noted that this contradicted Grünenthal's submission that in the last quarter of 2015 and in 2016 there was no expectation with regard to non-target activity.

The 2015 Grünenthal Sales Team Incentive Scheme stated that the Palexia SvT and Versatis SvT quarterly targets were set per business unit by the CDMT. Quarterly targets were set per account by the business unit. These were managed to ensure, amongst other things that there was an equal challenge per representative. This enclosure also stated that the daily interaction rate was at least 5/day to include face to face meeting interactions named and unnamed target and not target customers. There was no mention of the Code requirements in this presentation.

The Panel noted Grünenthal's submission that it discovered that three out of 56 representatives registered more than three cold calls with the same individual health professional over a calendar year (this affected 15 individual health professionals with 4-6 interactions logged as cold calls). According to Grünenthal each representative insisted that he/she had entered the majority of their calls erroneously as cold calls indicating that there had been an error in call recording within the CRM system as opposed to an error in customer facing activity; each provided confirmation to support these calls as 'requested return visits' where relevant, such that no more than three cold calls were conducted on any individual health professional.

The Panel noted that three representatives out of 25 who had started in 2014 and 2015 had not logged any cold calls when they first started seeing customers; they were confused about the definition of a cold call. Two of the three said they thought that if they were invited by a receptionist or a secretary to return at a specified time to see a health professional, this would then be classed as a 'requested return visit'. According to Grünenthal this was not Grünenthal's internal standard, nor what was detailed during internal CRM training. The third individual said she incorrectly thought the 'requested return' option was to record an invitation for a future meeting (ie the health professional requested a return visit). The three representatives had not accurately recorded their interactions in the CRM system so Grünenthal did not have a clear oversight, but each representative maintained that he/she did not conduct more than three cold calls on any given individual.

The Panel further noted Grünenthal's definitions of a 'cold call' ie a call where no prior arrangement had been made to visit/re-visit the health professional, and a 'requested return visit', used when the health professional had agreed to, or made arrangements for the representative to return to continue agreed business objectives.

The Panel noted its comments above, the training/briefing provided by Grünenthal to its representatives together with the company's definitions of 'cold call' and 'requested return visit' and understood why representatives might be confused with how to record certain activities.

The Panel noted that whilst some documents provided by Grünenthal included the relevant Code requirements, others did not. The Panel noted that each of these documents had to standalone.

The Panel was concerned about Grünenthal's submission that as the majority of its representatives had worked the same territories with the same health professionals for a number of years, health professionals and representatives often formed relationships whereby the customer provided an invitation to a given representative to visit on a regular basis to maintain contact to ensure they remained up to date with therapy area and product developments to optimise their patient care, so they were aware of meetings and events led by or supported by Grünenthal, or to support broader understanding of clinical experience with Grünenthal products. The Panel noted Grünenthal's submission that these invitations might not be specific with reference to time or topic but were genuine and legitimate.

That a representative had a long standing relationship with a health professional when

combined with the activities cited by Grünenthal did not, in the Panel's view, mean that all subsequent calls were solicited as implied. Whether such a call was solicited would depend on a consideration of all the circumstances. Certainly in the Panel's view a 1:1 call in response to a broad open invitation without reference to time or topic was unlikely to be viewed as a solicited call.

The Panel was also concerned that a number of briefing documents, when referring to the Code and its supplementary information, qualified the requirement that there be no more than three unsolicited calls per year. For instance, the 2014 Commercial Team Standards activity twice when referring to the call limit stated 'However it is assumed a significant proportion of this historic industry activity was based on customer request'. It also stated with reference to the number of unsolicited calls that 'However it is assumed that a proportion of activity will be based on customer request'. Similar qualifications were repeated in the Commercial Directorate Standards' presentations for 2015 and 2016. In the Panel's view, this qualification was misleading and downplayed the importance of the restriction on the number of cold calls and might encourage representatives to proactively seek return calls such that they might not all be *bona fide* solicited calls.

The Panel noted all of its comments above. Grünenthal had failed to be sufficiently clear about how representatives could meet the cycle plan and comply with the Code. In addition, the Panel considered that Grünenthal had failed to provide its representatives with information that was sufficiently clear about the differences between call rates and contact rates within the context of the cycle plans and target interactions and the Panel ruled a breach of the Code.

The Panel, noting its comments and ruling above, considered that Grünenthal had failed to comply with its undertaking given in in Case AUTH/2652/11/13 and a breach of the Code was ruled.

Whilst the Panel had concerns, as noted above, there was, on balance, no evidence that representatives over called on health professionals as alleged and the Panel ruled no breach of the Code which was upheld on appeal by the complainant.

The Panel noted its comments above and considered that briefing provided by Grünenthal to its representatives regarding the definitions of call rates and requested return visits and its qualification of the requirement that there be no more than 3 unsolicited visits per year was such that it was likely to lead to a breach of the Code. A breach of the Code was ruled.

Noting its rulings above, the Panel considered that Grünenthal had failed to maintain high standards and a breach of the Code was ruled. The Panel noted that some efforts had been made to refer to the relevant requirements of the Code and comply with the undertaking but considered that overall these were insufficient. The Code requirements were not referred to in all relevant documents and where such references did appear they were insufficient as set out above. An undertaking was an important document. The Panel noted that inadequate action leading to a breach of undertaking was an example of an activity likely to be in breach of Clause 2. The Panel was concerned that following Case AUTH/2652/11/13, Grünenthal was still not sufficiently clear about the differences between call rates and contact rates as referred to in the relevant supplementary information within the context of representative's interactions and cycle plans. Bearing that in mind and noting its rulings above the Panel ruled a breach of Clause 2.

2 GP-PEP Programme

The Panel noted Grünenthal's submission that health professionals did not have to have prescribed Grünenthal medicines for a minimum number of patients before they could be selected as a speaker but Grünenthal expected speakers to have had at least some experience with their use so that they could refer to this when speaking, however no expectation was made in terms of the extent of their use. This was to ensure that speakers would be able to provide advice on how to select the right patient for different medicines, and how to treat to achieve the greatest potential pain relief. In principle, the Panel did not consider that this was unreasonable. The Panel also noted the working instruction which included the criteria upon which speakers were selected and the process for recruiting a speaker. Potential speakers should be medical doctors and/ or selected nurse or pharmacist prescribers who, *inter alia*, had experience prescribing Grünenthal products which was similar to earlier versions; no version of the working instruction required that a health professional prescribe Grünenthal medicines for a minimum number of patients to be selected as a speaker as alleged. On this narrow ground no breaches of the Code were ruled which were upheld on appeal by the complainant.

The Appeal Board noted that before a consultant provided a service a written contract or agreement, which specified the nature of the services to be provided and the basis for payment of those services, had to be signed in advance. The Appeal Board noted Grünenthal's submission that neither electronic nor hard copy contracts could be located for four speakers in 2014 and two in 2015. The Appeal Board ruled a breach of the Code.

With regard to the allegation that company compliance was poorly monitored as some consultants had spoken at meetings without a contract in place and some had not paid for services provided, the Panel noted Grünenthal's submission that a review of all GP-PEP meetings conducted in 2014, 2015, and 2016 (n = 271) found that 5 speaker agreements were signed after the meeting took place, therefore the Panel ruled a breach of the Code. The Panel considered that Grünenthal had failed to maintain high standards in this regard and a breach of the Code was ruled.

The Panel then considered the allegation that representatives were set a target number of

meetings to hold per quarter and although their bonus did not rely on this payment, it was listed as a key performance indicator and failure to achieve the target level of meetings each quarter resulted in a reduction, or in some cases, no annual pay rise. The Panel noted Grünenthal's submission that it had never set representatives a target number of meetings since the programme was established in 2012 and the number of meetings bore no impact on bonus or pay rise as alleged. The Panel noted that the onus was on the complainant to prove his/her complaint on the balance of probabilities and the Panel considered that there was no evidence in this regard. The Panel thus ruled no breach of the Code which was upheld on appeal by the complainant.

The Panel noted its rulings above and decided that a ruling of Clause 2 which was reserved as a sign of particular censure was not warranted in this instance and no breach of that clause was ruled which was upheld on appeal by the complainant.

A contactable complainant, who wished to remain anonymous, complained about Grünenthal Ltd's practice and the pressure put on its sales representatives to perform in a manner which risked bringing the industry into disrepute.

COMPLAINT

The complainant stated that in the past a complaint was made about Grünenthal and its expected call rates on health professionals which he/she understood was upheld.

The complainant alleged that Grünenthal's defence in that case that sales representatives were not incentivised on achieving call rates could not be further from the truth. The complainant alleged that sales representatives' bonus payments were based on unethical call rate expectations.

At the start of each quarter representatives listed their 'target customers' and how many times they would be seen the following quarter. The complainant understood that even stating that Grünenthal would see each of those customers once in each quarter was a breach of the Code which allowed three calls per year. The complainant stated that Grünenthal was not happy with one call per customer per quarter. The list was checked by the customer relationship management (CRM) champion who discussed issues with a senior employee before passing the cycle plans. It was openly stated that experienced representatives should not just be entering in '1's' down the list. This led to some representatives stating that they would see particular health professionals more than eleven times in a four month period. This was compounded by the fact that even if the said representative achieved in excess of their sales vs target, if they did not achieve a minimum percentage of the cycle plan that was put in place they would not receive any bonus payment. This led to both the falsifying of calls and some representatives reporting more than twenty calls on one single doctor in a three month period.

Representatives were told to record calls as 'requested return visit' on the CRM system. This could never be true for new representatives making their first calls but they were told to record them in this way anyway.

The complainant explained that Grünenthal also ran a GP pain education programme (GP-PEP). The sales representatives were to ask health professionals to act as paid speakers for these meetings. However, unless the health professional had prescribed the product they were required to speak on (most often Palexia (tapentadol hydrochloride)) to a minimum number of patients, they were not permitted by the company to speak. The company compliance was poorly monitored as some consultants had spoken at meetings without a contract in place. Grünenthal had also failed to pay consultants for services provided.

Representatives were then set a target number of meetings to hold per quarter. Again, although their bonus did not rely on this payment, it was listed as a key performance indicator and failure to achieve the target level of meetings each quarter resulted in a reduction, or in some cases, a complete removal of an annual pay rise.

When writing to Grünenthal, the Authority asked it to consider the requirements of Clauses 2, 9.1, 15.4, 15.9 and 29 of the Code with regard to the conduct of representatives. With regard to the GP-PEP Programme the Authority asked it to consider the requirements of Clauses 2, 9.1, 18.1 and 23.1. The case would be considered under the requirements of the Code relevant to the time the activities took place. Clause 23 of the current Code was Clause 20 in the Second 2012 Edition of the Code and the 2014 Code.

RESPONSE

Grünenthal addressed each matter in turn.

1 Activity targets for representatives

Grünenthal submitted that activity targets were established as part of overall 'cycle plans' as part of overall account planning. An overall summary of the principles were provided. Cycle plans were created by each individual representative (known internally as account representatives (ARs) or account managers (AMs); previously pain sales managers, (PSMs)) based on their own local knowledge of what was required to drive business. The cycle plans were created and finalised in collaboration with any relevant cross-functional colleagues who might be working in the same localities to ensure complementary activities.

In 2014 and 2015, there were four cycle periods per year. In 2016 and moving forward, there were three cycle periods per year. Before each new cycle period, sales representatives were sent a list of all health professionals on their territory from which they were required to create a list of target customers whom they identified to be important to their local business. The principles of targeted activity were described. Representatives were asked to conduct a review to identify the need for any changes to their list of target customers and amend accordingly. Examples of instructions provided to

representatives were provided. On average, each target list comprised over 100 customers dependent on the internal experience of the representative, local market access and geography (Grünenthal referred to an email as an example of communication in this regard). Representatives were asked to complete a prospective activity plan for the upcoming period for each individual target customer based a number of identified factors.

Grünenthal noted that 'activity' could take the form of a face-to-face (1:1) call with a specified individual, or contact established when the individual was a delegate at a meeting. Grünenthal did not set or incentivise expected call or contact rates, instead this general collective 'activity' was monitored.

The total number of interactions planned per individual target customer was established by the representative themselves based on what they had the potential to achieve. This could be zero, 1, 2, 3 … interactions over the cycle period, including calls requested by a customer (Grünenthal referred to its briefing materials which stated 'Replace the 1 in the 'Planned Calls' field with the number you are actually and compliantly planning (call contracts)'. Representatives were asked to plan those interactions themselves based on their own knowledge of their customers and local business. They were not driven by the company to plan a minimum number of interactions with any given individual health professional; decisions were made by the local representative.

The promotional teams were provided with a commercial standards document at the beginning of each year. Examples of 2015 and 2016 were provided. These documents clarified all business expectations including instructions to plan activity in line with the requirements of the Code, in addition to regular reminders within other communications.

In 2013, 2014, and the first three quarters of 2015, the interaction capacity per representative per day was set at a minimum of 2 target customers via face-to-face (1:1) call or contact at a meeting, plus a requirement to add 'non-target activity'. This generated a total of 5-7 expected interactions with health professionals per working day. This gave a volume of interactions to be achieved per period per employee and ensured representatives had a framework for their working day. Achievement of an individual's cycle plan was based on total actual volume of calls vs total target volume so no daily call rate was required nor stipulated.

In quarter 4 2015, the interaction capacity per day was increased to a minimum of 3 target customer interactions per day via face-to-face (1:1) calls or through contact at a meeting. There was no expectation with regards non-target activity in that quarter. Achievement of the cycle plan was based on total actual volume versus total target volume so there was no daily call rate required nor stipulated.

Three cycle plans per annum with a duration of four months per cycle were introduced in 2016, C1, C2 and C3. For 2016 C1, the interaction capacity per day was set at a minimum of 3 target customer interactions per day, via a face-to-face (1:1) call or a meeting. There was no expectation with regards non-target activity. This gave a volume of interactions to be achieved per target customer per period per employee. Achievement of the cycle plan was based on total actual volume vs total target volume so no daily call rate was required.

Once the provisional cycle plans were created by individual representatives, they were reviewed and/or challenged by line managers based on reasonable potential to attain the plan proposed, and adherence to compliance requirements. There was no additional review or approval step outside of this as alleged by the complainant. Once the validation exercise was completed, the cycle plans were uploaded into the CRM system and the team started activity to achieve them. Data was extracted and reviewed regularly so the teams could see their progress towards their cycle plan attainment but it should be noted that activity was only one component of overall cycle plans. (Grünenthal referred to examples of internal communications regarding the performance and attainment of cycle plans.)

Grünenthal therefore refuted any allegation that it had driven activity with health professionals that exceeded the requirements of Clause 15.4 which was supported by its briefing material that did not advocate, either directly or indirectly, any course of action that would be likely to lead to a breach of the Code (Clause 15.9).

How Grünenthal bonused activity targets for sales representatives since January 2014

The 2013 incentive scheme was based on several measures and details were provided. There were no activity parameters in the 2013 scheme.

The 2014 incentive scheme was based on several measures in addition to growth and sales. A pre-qualifier was introduced based on activity volume, but not on any daily call rate. It used the representative self-created cycle plans to ensure that activity was taking place within target areas rather than on any accessible customer. To qualify the representative had to achieve a minimum 90% of their quarterly cycle plan activity.

The initial incentive scheme in 2015 included pre-qualifying criteria to attain 90% cycle plan volume. In May 2015, the H1 scheme was retrospectively amended to remove the activity component. The second half of 2015 did not have any activity measures.

Initial 2015 incentive scheme included pre-qualifying criteria: 90% volume attainment of cycle plans, minimum interaction rate 5 per day but this was removed from the updated 2015 incentive scheme.

The 2016 incentive scheme was based on several measures including achieving a minimum 90% of their cycle plan (volume of actual calls/volume of planned calls). This was not based on any daily call rate.

Grünenthal submitted that as was evidenced above, and contrary to the accusation made by the complainant, Grünenthal had never stipulated that 'the primary factor in sales representatives receiving their bonus payments was … based on unethical call rate expectations'.

Grünenthal noted that the complainant alleged that 'even stating you will expect to see each of those customers once in each quarter is already on [sic] breach of the codes guide of 3 calls in a year'. The requirements stipulated in the supplementary information to Clause 15.4 specified that 'the number of calls made on a doctor or other prescriber by a representative each year should not normally exceed three on average'. This did not cover the planning of calls with specific individual customers based on existing relationships, ongoing projects and following customer requests so Grünenthal disagreed with the allegation made in that regard.

Grünenthal noted that the complainant further alleged that 'Grünenthal are not happy with representatives just stating one call per customer per quarter', and alleged a review of submitted cycle plans by the CRM Champion and a senior employee. The default activity against all customers when working on a draft cycle plan was '1'. Representatives were instructed to increase or decrease this number accordingly for individual health professionals in order to create their overall cycle plan. The acceptance of '0' and '1' was described in briefing material sent to representatives (examples were provided in briefing materials and additional notes section of internal communications). A review of submitted cycle plans was not conducted by the CRM Champion and a senior employee as alleged.

Grünenthal submitted that there were no activity parameters in the 2013 scheme at all, daily call rate or other (Grünenthal referred to the Grünenthal Sales Incentive Scheme 2013.

Grünenthal submitted that its response to Case AUTH/2652/11/13 was correct, complete and reflective of the situation in 2013. There was no incentive on any activity (including call rates) in the 2013 scheme, just Palexia growth and Versatis SvT. Grünenthal submitted that it did not provide a false response to Case AUTH/2652/11/13, nor did it fail to comply with its undertaking.

Grünenthal conducted a review of 1:1 call data within the CRM system in response to this complaint. It was identified that three representatives out of 56 registered more than three cold calls with the same individual health professional over a calendar year (this affected 15 individual health professionals with 4-6 interactions logged as cold calls). Each of these representatives were spoken to during an internal investigation and provided notes to support the visits they logged. Each insisted that they had entered the majority of their calls erroneously as cold calls and provided a breakdown accordingly. This was therefore indicative that there had been an error in call recording within the CRM system as opposed to an error in the customer facing activity of these representatives. As each provided confirmation to support these calls as 'requested return visits' where relevant, such that no more than three cold calls were conducted on any individual health professional by a Grünenthal representative, there was no evidence to suggest that there had been a breach of Clause 15.4.

Grünenthal submitted that all new representatives received training on how to use the CRM system when they started. The training presentation delivered to the most recent group of new starters in February 2016 was provided. The logging of calls and use of the drop-down menu to record whether a call was a cold call or a requested return visit was detailed on slide 49. The presentation was delivered by senior managers who provided a concurrent demonstration of functionality in the test system whilst using the slides on a separate screen during training sessions. Whilst the use of the drop-down menu was not detailed on slide 49, it was discussed and demonstrated during training.

A review of activities logged in the CRM system by all new starters to promotional field based roles in 2014 and 2015 was conducted upon receipt of this complaint. Of the 25 field based promotional staff who started with Grünenthal in 2014 or 2015, three had not logged any cold calls when they first started seeing customers.

When these individuals were contacted during the internal investigation, they described being confused in their understanding of what a cold call was. Two of the three said they thought that if they were invited by a receptionist or a secretary to return at a specified time to see a health professional, this would then be classed as a 'requested return visit' rather than a cold call. This was not Grünenthal's internal standard, nor what was detailed during internal CRM system training. The third individual said she incorrectly thought the 'requested return' option was to record an invitation for a future meeting (ie the health professional requested a return visit).

The territories for each of the identified individuals did not lend themselves to easy speculative calls so each had said that only approximately 10% of their contact time with health professionals was based on cold calls. Unfortunately, they had not accurately recorded their interactions in the CRM system for the company to have a clear oversight, but each maintained that they did not conduct more than three cold calls on any given individual. Grünenthal therefore identified an error in record keeping by three individuals as opposed to the conduct of activity that was in breach of the requirements of Clause 15.4. Grünenthal submitted that this was not indicative of a failure to maintain high standards by the individual representatives, nor the company, as the error rested in record keeping, not inappropriate over calling on individual health professionals. Grünenthal did not have any evidence to indicate that any of those representatives over called on any individual health professional as each confirmed that they had not. Each of the individuals received one-to-one re-training from their line manager on the definitions to apply when recording calls within

the CRM system so the records accurately reflected activities in the field.

In summary Grünenthal submitted that it was asked to respond in relation to Clauses 2, 9.1, 15.4, 15.9 and 29. Grünenthal refuted the allegations made against each of these clause requirements as outlined above.

In response to a request for further information Grünenthal submitted that it required all interactions between Grünenthal staff and health professionals or other relevant decision makers to be logged within 24 hours of the interaction in the CRM system. When a face-to-face contact was recorded, the nature of the interaction must be recorded using options from a drop-down menu in order for the activity to be logged and was a mandatory field in the system. There were two options that might be selected:

- 'cold call' ie a call where no prior arrangement had been made to visit/re-visit the health professional, or
- 'requested return visit', used when the health professional had agreed to, or made arrangements for the representative to return to continue agreed business objectives.

An image of the CRM system was provided. Grünenthal submitted that functionality of the system allowed a plethora of reports to be run on any information entered across the UK business as a whole, at an individual representative level, or against an individual health professional, including the number of cold calls logged. Reports could be run by users or centrally (certain roles had access to enhanced reports, eg CRM Manager, Head of Sales, Head of Compliance, amongst others).

Grünenthal submitted that it proactively provided all new starters with training on the requirements of the Code on commencement of employment and continued to do so at regular intervals. Specific training on interactions with health professionals and the recording of calls in the CRM system (including the annual limit of unsolicited calls per individual health professional) was provided during training on the CRM system. Regular briefing documents reinforced this training on an ongoing basis as previously described and evidenced.

Grünenthal submitted that for the benefit of better and long-lasting business opportunities, it preferred its customer facing staff to form solid relationships with customers, rather than assume a 'scatter-gun' coverage approach to appointments. Grünenthal wished to hold relationships with health professionals who had a clinical interest or responsibility in the management of pain. As such, there were various reasons why a significant proportion of customer-facing activity should be focussed on ongoing projects and plans at customer request: reviewing emerging data within the therapy area or data specific to Grünenthal products, developing and supporting formulary submissions, making arrangements to present data to broader teams, making arrangements for customers to share their experience with other clinicians as a speaker at meetings, discussing medical educational goods and services etc.

Grünenthal submitted that there was a greater value for both health professional and Grünenthal in interactions such as these rather than old style 'cold calls', therefore Grünenthal wished its representatives to focus on those quality relationships and interactions instead of simply knocking on doors. Activity associated with projects was not seen to be unsolicited when there was an existing arrangement with the health professional for follow-up discussions/calls.

Grünenthal submitted that there were many plans and projects designed with the input of health professionals for the benefit of the NHS and patients at a local, regional or national level. Those individual health professionals would have a close ongoing relationship with their primary Grünenthal contact in order to execute or support those plans and projects.

Grünenthal noted that the supplementary information to Clause 15.4 described attendance at meetings, a visit requested by a doctor or other prescribers, calls made in order to respond to a specific enquiry, and a visit to follow up a report of an adverse event, as exceptions to the limit of three cold calls per annum. Calls associated with ongoing projects, discussion of speaker engagements, development of formulary submissions and the like were not unsolicited as there was an existing arrangement with given health professionals, and were examples of calls that were requested by the health professional, sometimes in order to respond to a specific enquiry.

Grünenthal submitted that the majority of its representatives had worked the same territories with the same health professionals for a number of years. Over such a period of time, health professionals and representatives often formed relationships whereby the customer provided an invitation to a given representative to visit on a regular basis to maintain contact. This might be to ensure they remained up to date with therapy area and product developments to optimise their patient care, they were aware of meetings and events led by or supported by Grünenthal, or to support broader understanding of clinical experience with Grünenthal products. Grünenthal submitted that whilst these invitations might not be specific with reference to time or topic, they were genuine and legitimate.

Grünenthal submitted that its reference to 'existing relationships' covered all such engagements related to project work and when a non-specific invitation was offered by a health professional to a representative to maintain contact.

2 GP-PEP

Grünenthal submitted that the criteria upon which speakers were selected were described in the working instruction (WIN) for the conduct of PEP meetings. Grünenthal noted that there was an internal change in name of these meetings from 'GP-PEP meetings' when the programme started in 2012 to 'PEP meetings' in 2015.

The current version of WIN was provided as were the 'recruiting a GP-PEP speaker' sections of previous versions:

'Recruiting a PEP speaker

AR/AMs overseen by the RAMs or RAMs on their own are responsible for the recruitment of PEP speakers. There must be a strong rational for the recruitment of speakers (see criteria below).

Criteria for potential speakers:

- Speakers should be medical doctors and/or selected nurse or pharmacist prescribers who are
  - o experts in pain management,
  - o be locally regarded as experts in their area of practice,
  - o have current experience prescribing GRT products,
  - o be willing to speak about their experience with GRT products as part of each PEP meeting,
  - o have good presentation skills,
  - o be able to commit to presenting at 2-3 meetings a year (minimum).
- Speakers must be local. A national speaker may be used if no speaker is currently available within the local geography.
- Product data training will be provided by the local MSL close to the date of the speaker's first meeting and updates provided as and when required.
- Training must not be provided unless a meeting is planned for them to speak at.
- Potential speakers must be made aware that PEP meetings are promotional meetings and therefore subject to the requirements of the ABPI Code.'

Version 1 of the WIN effective April 2012 did not specify criteria for selecting a speaker. Two examples of the speaker justification forms were provided.

Grünenthal submitted that whilst interacting with health professionals, its representatives might identify that a certain individual had the potential to be suitable to speak on behalf of the company at promotional meetings. Representatives must have agreement from their line manager in order to progress before any discussions were had with the health professional.

A selection of different versions of speaker agreement forms and speaker briefing documents were provided. The 'New PEP Speaker Standard Introduction email' was also provided (dated February 2015).

Grünenthal submitted that as demonstrated within all versions of its WIN, health professionals did not have to have prescribed Grünenthal medicines for a described minimum number of patients before they could be selected as a speaker. As these meetings were promotional meetings for Grünenthal products, Grünenthal expected them to have had at least some experience with their use so they could refer to this when speaking, however no expectation was made in terms of the extent of their use. This ensured they would be able to provide advice on how to select the right patient for different medicines, and how to treat a patient to achieve the greatest potential pain relief. With no experience of using Grünenthal products, speakers would not have the necessary insight and expertise expected by delegates attending such meetings, and the validity of such meetings would be drawn into question.

As described above, and demonstrated within all versions of the WINs, Grünenthal submitted that there was no minimum number of patients for whom health professionals had to have prescribed Grünenthal products to in order to be recruited as a speaker. Speakers must be experts in pain management and have adequate experience to discuss case studies.

Grünenthal submitted details of the average payments made to speakers and chairpersons providing services to support the GP-PEP/PEP programme in 2014 and 2015. These figures were inclusive of any preparatory work that had been undertaken in addition to speaking services at the GP-PEP/PEP meeting.

A review was conducted of all GP-PEP and PEP meetings conducted in 2014, 2015, and 2016 to date in response to this complaint. The total number of meetings conducted over this period was 271. During the review, it was found that 5 speaker agreements were signed after the meeting took place. One was signed in advance of the meeting date on an app that was being trialled but the signature did not properly load therefore a hard copy contract was signed after the event in order to allow payment to be processed. Two were signed after the event due to miscommunication between two members of staff, each of whom believed the other to be responsible for obtaining the signature. One was signed the day after the event due to a lack of oversight by the meeting organiser. One was signed after the event when numerous attempts to ask the speaker to sign the contract in advance of the meeting were not responded to by the speaker.

Grünenthal submitted that whilst it was disappointed to report that it found any contracts that were not signed in advance of the meeting date, it did not believe this low overall figure (<2% of total) to indicate a systematic failure of the company to adhere to high standards (Clause 9.1).

Contrary to what had been alleged by the complainant, Grünenthal submitted that it had never set representatives a target number of meetings to hold per quarter since the GP-PEP/PEP programme was established. Grünenthal preferred the investment of time and effort be afforded in areas where the meetings would be genuinely useful rather than working solely to the achievement of metrics. This also meant that the number of meetings completed by a representative bore no impact on their bonus or annual pay rise as alleged. Within the priorities identified for all representatives, Grünenthal included the statement 'PEP, KnEx and speaker meeting goals are achieved as agreed with the line manager', but this referred to the conduct of such meetings rather than an arbitrary number of meetings that must be delivered.

Unfortunately there were five instances whereby speaker contracts were not signed with speakers in advance of their speaking services, however in the context of the number of speaker meetings held over this period (271), Grünenthal did not believe that this indicated a failure to maintain high standards (<2% of total). Grünenthal submitted that its selection process for recruiting speakers to present at promotional meetings on its behalf was not in breach of the requirements of Clause 18.1. Thereby it refuted that any of its activities in this regard were in breach of Clause 2.

General summary

Grünenthal submitted that since it was notified of this complaint, some of its employees had been contacted and told that this complaint was made by one of those ex-employees. Grünenthal's employees were deeply upset that the company was being targeted by these ex-employees.

Grünenthal reiterated its commitment to adhering to the Code in both the letter and spirit and was disappointed to have received this complaint however it was confident that its activities were in line with the requirements of the Code.

PANEL RULING

The Panel noted that the complainant had the burden of proving their complaint on the balance of probabilities. The complainant had not provided any material to support his/her allegations but had provided a detailed account of their concerns. Further the complainant had not given details of the dates regarding his/her allegations. The case preparation manager had informed Grünenthal that the case would be considered under the Code relevant to the time that activities took place and had asked for details and copies of materials etc for representatives in the past two years.

1 Activity targets for representatives

The Panel noted that Clause 15.4 of the 2016 and 2015 Codes required representatives to ensure that the frequency, timing and duration of calls on, *inter alia*, health professionals, together with the manner in which they were made, did not cause inconvenience. (The 2014 Code had similar requirements but the clause referred to appropriate administrative staff rather than other relevant decision makers). The supplementary information to that clause stated, *inter alia*, that companies should arrange that intervals between visits did not cause inconvenience. The number of calls made on a doctor or other prescriber by a representative each year should normally not exceed three on average excluding attendance at group meetings and the like, a visit requested by the doctor or other prescriber or a visit to follow up a report of an adverse reaction. Thus although a representative might speculatively call upon or proactively make an appointment to see a doctor or other prescriber three times on average in a year, the annual number of contacts with that health professional might be more than that. The supplementary information to Clause 15.4 also advised that when briefing representatives companies should distinguish clearly between expected call rates and expected contact rates. Targets must be realistic and not such that representatives breached the Code in order to meet them. Clause 15.9 stated that briefing material must not advocate directly or indirectly any course of action which would be likely to lead to a breach of the Code.

The Panel disagreed with Grünenthal's submission that Clause 15.4 did not cover the planning of calls with specific individual customers based on existing relationships.

Case AUTH/2652/11/13 concerned an email sent by a senior employee to remind the sales force to enter data into a customer relationship management (CRM) system [Advance] daily and to instruct representatives on expected call rates. The complainant noted that the email only referred to interactions and thus failed to reflect the Code which stated 'When briefing representatives, companies should distinguish clearly between expected call rates and expected contact rates'. Grünenthal was ruled in breach of Clause 15.4 on the narrow ground alleged because the email in question was not sufficiently clear about the differences between call rates and contact rates as referred to in the relevant supplementary information.

Turning to the case now before it, Case AUTH/2823/2/16, the Panel noted Grünenthal's submission that activity targets were established as part of overall cycle plans which were part of overall account planning. The Panel further noted Grünenthal's submission that 'activity' could take the form of a face-to-face (1:1) call with a specified individual, or contact established when the individual was a delegate at a meeting. The Panel noted Grünenthal's submission that it did not set or incentivise expected call or contact rates, instead it was the general collective 'activity' that was monitored.

The Panel noted that although a representative might call on a doctor or other prescriber three times in a year the number of contacts with that health professional in the year might be more than that provided it was made clear that only three of those contacts could be cold calls. Without this explanation, instructions to representatives regarding interactions might advocate a course of action which was likely to breach the Code. The Panel noted that Grünenthal could organise its sales force as it saw fit but, nonetheless, had to ensure that interactions with health professionals and instructions to representatives complied with the Code. In the Panel's view companies needed to be especially cautious and therefore clear and unambiguous about Code requirements when they used terms such as 'interaction' and 'activity' which differed from the language used in the Code.

The Panel noted Grünenthal's submission that cycle plans were created by each individual representative based on their own local knowledge of what was required to drive business and the total number of interactions planned per individual target customer

was also established by the representative based on what they had the potential to achieve, and could be zero, 1, 2, 3 etc… interactions over the cycle period, including calls requested by a customer; they were not driven by the company to plan a minimum number of interactions with any given individual health professional. The Panel noted Grünenthal's submission that the default activity against all customers when working on a draft cycle plan was '1'. Representatives were instructed to increase or decrease this number accordingly for individual health professionals in order to create their overall cycle plan. The acceptance of '0' and '1' was described in briefing material sent to representatives.

Once the provisional cycle plans were created they were reviewed and/or challenged by line managers based on reasonable potential to attain the plan proposed, and adherence to compliance requirements. The Panel noted Grünenthal's submission that there was no additional review or approval step outside of this.

The Panel noted Grünenthal's submission regarding cycle plans, and how they had changed over the years. In 2013, 2014 and the first three quarters of 2015, the interaction capacity per day was set at a minimum of 2 target customers, via face to face (1:1) call or contact at a meeting, plus a requirement to add 'non-target activity' which generated a minimum of 5-7 expected interactions with health professionals per working day. In quarter 4 of 2015 and in 2016, this increased to a minimum of 3 target customer interactions per day and there was no expectation with regard to non-target activity. The Panel noted Grünenthal's submission that achievement of an individual's cycle plan each year was always based on total actual volume of calls vs total target volume so no daily call rate was required or stipulated. The complainant had not mentioned a daily call rate as implied by Grünenthal. Three cycle plans per annum with a duration of four months per cycle were introduced in 2016 as opposed to four cycles of three months previously.

The Panel considered that Grünenthal's submission that no daily call rate was required was not wholly accurate. Representatives were given a minimum interaction capacity per day and representatives' provisional cycle plans were reviewed and challenged by line managers then validated. An email dated 2 May 2014 from the commercial director to the sales force made it clear that a key performance indicator on the cycle plan data was the daily rate of work that the quarterly volume of contacts delivered. In the Panel's view, the number of expected daily interactions would include, over the cycle plan, calls on target customers and others.

The Panel noted Grünenthal's submission regarding how activity targets were bonused. A pre-qualifier based on activity volume, but not on any daily call rate, was introduced in 2014 to be eligible for the bonus scheme. It used the representatives' self-created cycle plans to ensure that activity was taking place within target areas rather than on any accessible customer. To qualify the representative had to achieve a minimum 90% of their quarterly cycle plan activity.

An additional Palexia growth element was added for the second half of 2014 but did not stipulate any activity inputs or pre qualifiers. The initial incentive scheme in 2015 included pre-qualifying criteria to attain 90% cycle plan volume but in May 2015, the scheme was retrospectively amended to remove the activity component which was re-introduced in 2016.

The Panel noted that the Grünenthal promotional teams were provided with a commercial standards document at the beginning of each year which clarified business expectations including instructions to plan activity in line with the requirements of the Code, in addition to reminders within other communications. The Commercial Directorate Standards 2015 and 2016 presentations defined a call as a one to one event with a customer and a contact as being a call or a meeting event. The documents further stated that CRM recorded customer interactions which was an internal term defined as a face-to-face call or meeting with a customer and on the same slide stated 'Our anticipated activity rates take into account the PMCPA code of conduct [respective year] and each customer should not have more than 3 unsolicited calls per year. However it is assumed a significant proportion of this activity will be on customer request'. The slide concluded that other activity could take place outside of the target lists and cycle plan and detailed that Grünenthal was resourced to deliver 5-7 total customer contacts per customer facing day. The 2016 slide stated in addition and that this activity should not compromise the target activity achievement. The Panel queried how and where this other activity taking place outside of the target lists and cycle plans would be recorded. The Panel also noted that this contradicted Grünenthal's submission that in the last quarter of 2015 and in 2016 there was no expectation with regard to non-target activity.

The 2015 Grünenthal Sales Team Incentive Scheme stated that the Palexia SvT and Versatis SvT quarterly targets were set per business unit by the CDMT. Quarterly targets were set per AR account by the business unit. These were managed by the RAM to ensure, amongst other things that there was an equal challenge per AR. This enclosure also stated that the daily interaction rate was at least 5/day to include face to face meeting interactions named and unnamed target and not target customers. There was no mention of the Code requirements in this presentation.

The Panel noted Grünenthal's submission that it discovered that three out of 56 representatives registered more than three cold calls with the same individual health professional over a calendar year (this affected 15 individual health professionals with 4-6 interactions logged as cold calls). According to Grünenthal each representative insisted that he/she had entered the majority of their calls erroneously as cold calls indicating that there had been an error in call recording within the CRM system as opposed to an error in customer facing activity; each provided confirmation to support these calls as 'requested return visits' where relevant, such that no more than three cold calls were conducted on any individual health professional.

The Panel noted that three representatives out of 25 who had started in 2014 and 2015 had not logged any cold calls when they first started seeing customers; they were confused about the definition of a cold call. Two of the three said they thought that if they were invited by a receptionist or a secretary to return at a specified time to see a health professional, this would then be classed as a 'requested return visit' rather than a cold call. According to Grünenthal this was not Grünenthal's internal standard, nor what was detailed during internal CRM training. The third individual said she incorrectly thought the 'requested return' option was to record an invitation for a future meeting (ie the health professional requested a return visit). The three representatives had not accurately recorded their interactions in the CRM system so Grünenthal did not have a clear oversight, but each representative maintained that he/she did not conduct more than three cold calls on any given individual.

The Panel noted Grünenthal's submission that the logging of calls and use of the drop-down menu to record whether a call was a cold call or a requested return visit was detailed on slide 49 of a training presentation delivered by the sales force effectiveness manager and CRM manager to the most recent group of new starters. The Panel noted Grünenthal's contradictory submission that whilst the use of the drop-down menu was not detailed on slide 49, it was discussed and demonstrated during training.

The Panel further noted Grünenthal's definitions of a 'cold call' ie a call where no prior arrangement had been made to visit/re-visit the health professional, and a 'requested return visit', used when the health professional had agreed to, or made arrangements for the representative to return to continue agreed business objectives.

The Panel noted its comments above, the training/briefing provided by Grünenthal to its representatives together with the company's definitions of 'cold call' and 'requested return visit' and understood why representatives might be confused with how to record certain activities. The Panel queried how many other representatives might be recording calls incorrectly due to confusion that was not identified during the review.

The Panel noted that whilst some documents provided by Grünenthal included the relevant Code requirements, others did not. The Panel noted that each of these documents had to standalone.

The Panel was concerned about Grünenthal's submission that as the majority of its representatives had worked the same territories with the same health professionals for a number of years, health professionals and representatives often formed relationships whereby the customer provided an invitation to a given representative to visit on a regular basis to maintain contact to ensure they remained up to date with therapy area and product developments to optimise their patient care, or they were aware of meetings and events led by or supported by Grünenthal, or to support broader understanding of clinical experience with Grünenthal products. The Panel noted Grünenthal's submission that these invitations might not be specific with reference to time or topic but were genuine and legitimate.

That a representative had a long standing relationship with a health professional when combined with the activities cited by Grünenthal did not, in the Panel's view, mean that all subsequent calls were solicited as implied. Whether such a call was solicited would depend on a consideration of all the circumstances of the case. Certainly in the Panel's view a 1:1 call in response to a broad open invitation without reference to time or topic was unlikely to be viewed as a solicited call under Clause 15.4 and its supplementary information.

The Panel was also concerned that a number of briefing documents, when referring to Clause 15.4 and its supplementary information, qualified the requirement that there be no more than three unsolicited calls per year. For instance, the 2014 Commercial Team Standards activity twice when referring to the call limit stated 'However it is assumed a significant proportion of this historic industry activity was based on customer request'. It also stated with reference to the number of unsolicited calls that 'However it is assumed that a proportion of activity will be based on customer request'. Similar qualifications were repeated in the Commercial Directorate Standards' presentations for 2015 and 2016. In the Panel's view, this qualification was misleading and downplayed the importance of the restriction on the number of cold calls and might encourage representatives to proactively seek return calls such that they might not all be *bona fide* solicited calls.

The Panel noted all of its comments above. Grünenthal had failed to be sufficiently clear about how representatives could meet the cycle plan and comply with the supplementary information to Clause 15.4. In addition, the Panel considered that Grünenthal had failed to provide its representatives with information that was sufficiently clear about the differences between call rates and contact rates within the context of the cycle plans and target interactions as referred to in the supplementary information to Clause 15.4 of the Code. The Panel ruled a breach of Clause 15.4.

The Panel noted the narrow ground of its ruling in Case AUTH/2652/11/13 wherein the complainant had alleged that an email only referred to interactions and thus failed to reflect the Code in relation to distinguishing between expected call and contact rates. A breach was ruled on the narrow ground alleged. Turning to the present case, the Panel noting its comments and ruling above considered that Grünenthal had failed to comply with its undertaking given in in Case AUTH/2652/11/13 and a breach of Clause 29 was ruled.

Whilst the Panel had concerns, as noted above, about Grünenthal's briefing of its representatives with regard to the requirements of Clause 15.4 and how calls were being logged and it noted that certain years required representatives to achieve 90% of their quarterly cycle plan to qualify for the bonus scheme, they were created based on an expected number of interactions per day as set by Grünenthal,

the Panel noted that there was no evidence before it that representatives had falsified calls and whilst the Panel was concerned about the effect of the material on representatives' behaviour, there was, on balance, no evidence that representatives over called on health professionals contrary to the requirements of Clause 15.4 as alleged and the Panel ruled no breach of that clause.

The Panel noted that Clause 15.9 required, *inter alia*, companies to prepare detailed briefing material for medical representatives on the technical aspects of each medicine which they will promote. Briefing material 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 its comments above and considered that briefing provided by Grünenthal to its representatives regarding the definitions of call rates and requested return visits and its qualification of the requirement that there be no more than 3 unsolicited visits per year was such that it was likely to lead to a breach of the Code. A breach of Clause 15.9 was ruled.

Noting its rulings above, the Panel considered that Grünenthal had failed to maintain high standards and a ruling of Clause 9.1 was ruled. The Panel noted that some efforts had been made to refer to the relevant requirements of the Code and comply with the undertaking but considered that overall these were insufficient. There were some references to the supplementary information to Clause 15.4 in some of the newsletters. Such newsletters largely dealt with administrative matters and the technical requirements of setting up and organising a cycle plan online rather than representatives' field activity. The Code requirements were not referred to in all relevant documents and where such references did appear they were insufficient as set out above. An undertaking was an important document. The Panel noted that inadequate action leading to a breach of undertaking was an example of an activity likely to be in breach of Clause 2. The Panel was concerned that following Case AUTH/2652/11/13, Grünenthal was still not sufficiently clear about the differences between call rates and contact rates as referred to in the relevant supplementary information within the context of representative's interactions and cycle plans. Bearing that in mind and noting its rulings above the Panel ruled a breach of Clause 2.

2 GP-PEP

The Panel noted that Clause 18.1 required that no gift, pecuniary advantage or benefit may be supplied, offered or promised to members of the health professions or to other relevant decision makers in connection with the promotion of medicines or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine, subject to the provisions of Clauses 18.2 and 18.3. Clause 23.1 stated, *inter alia*, that the hiring of consultants to provide the relevant service must not be an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.

The Panel noted Grünenthal' submission that health professionals did not have to have prescribed Grünenthal medicines for a described minimum number of patients before they could be selected as a speaker but Grünenthal expected speakers to have had at least some experience with their use so that they could refer to this when speaking, however no expectation was made in terms of the extent of their use. This was to ensure that speakers would be able to provide advice on how to select the right patient for different medicines, and how to treat to achieve the greatest potential pain relief. In principle, the Panel did not consider that this was unreasonable. The Panel also noted the working instruction for the conduct of PEP meetings submitted by Grünenthal included in the list of criteria for potential speakers that they should be medical doctors and/or selected nurse or pharmacist prescribers who, *inter alia*, had experience prescribing Grünenthal products which was similar to earlier versions; no version of the working instruction required that a health professional prescribe Grünenthal medicines for a minimum number of patients to be selected as a speaker as alleged. On this narrow ground no breach of Clauses 18.1 and 23.1 was ruled.

With regard to the allegation that company compliance was poorly monitored as some consultants had spoken at meetings without a contract in place and Grünenthal had failed to pay consultants for services provided, the Panel noted Grünenthal's submission that a review of all GP-PEP meetings conducted in 2014, 2015, and 2016 (over 250) found that 5 speaker agreements were signed after the meeting took place. One was signed in advance of the meeting date on an app that was being trialled but the signature did not properly load therefore a hard copy contract was signed after the event in order to allow payment to be processed. Two were signed after the event due to miscommunication between two members of staff, each of whom believed the other to be responsible for obtaining the signature. One was signed the day after the event due to a lack of oversight by the meeting organiser. One was signed after the event when numerous attempts to ask the speaker to sign the contract in advance of the meeting were not responded to by the speaker. The Panel noted that Clause 23.1 of the current Code which was Clause 20 in the Second 2012 Edition of the Code and the 2014 Code required that, *inter alia*, a written contract or agreement must be agreed in advance of the commencement of the services which specified the nature of the services to be provided and the basis for payment of those services. The Panel did not know in which year the meetings were held where the speaker agreements were signed after the meeting took place but as the complaint was received before 1 May 2016, the Panel ruled a breach of Clause 20.1 of the Code as this was the same in the Second Edition of the 2012 Code, the 2014 Code and the 2015 Code. The Panel considered that Grünenthal had failed to maintain high standards in this regard and a breach of Clause 9.1 was ruled.

The Panel then considered the allegation that representatives were set a target number of meetings to hold per quarter and although their bonus did not rely on this payment, it was listed as a key performance indicator and failure to achieve

the target level of meetings each quarter resulted in a reduction, or in some cases, a complete removal of an annual pay rise. The Panel noted Grünenthal's submission that it had never set representatives a target number of meetings to hold per quarter since the GP-PEP/PEP programme was established in 2012 and the number of meetings completed by a representative bore no impact on their bonus or annual pay rise as alleged. The Panel noted that the onus was on the complainant to prove his/her complaint on the balance of probabilities and the Panel considered that there was no evidence in this regard. The Panel thus ruled no breach of Clause 9.1.

The Panel noted its rulings above and decided that a ruling of Clause 2 which was reserved as a sign of particular censure was not warranted in this instance and no breach of that clause was ruled.

APPEAL FROM THE COMPLAINANT

The complainant appealed all the Panel's rulings of no breach of the Code and provided additional evidence to support each of the original allegations as follows:

1 Activity targets for representatives

The complainant noted that the Panel had ruled no breach of Clause 15.4 as it had no evidence that representatives had over called on health professionals contrary to the requirements of that clause.

The complainant requested that the PMCPA interrogated Grünenthal's CRM system and cycle plans submitted in 2015 by a named representative, who during this time planned to call on a named doctor 11 times in one quarter. This was originally entered as a planned activity of 13 times in one quarter but was subsequently reduced to 11 by his line manager.

2 GP-PEP

With regard to the Panel's rulings of no breaches of Clause 18.1 and 23.1, the complainant alleged that emails were sent regarding the minimum requirements of prescribing to be met by consultants used for GP-PEP. The requirement clearly stated that consultants should have prescribed the given medicine to a minimum of 10 patients. Grünenthal had provided the working instruction only and not any copies of email correspondence regarding sign up of consultants. The complainant unfortunately did not have copies of those emails, however, he/she alleged that if such correspondence was requested Grünenthal would have had to make those available.

The complainant alleged that a named doctor from a named hospital spoke on behalf of Grünenthal at a meeting at a named hotel in July 2015, there was no contract in place and as far as the complainant was aware there was still no contract in place.

With regard to the Panel's ruling of no breach of Clause 9.1, it stated that there was no evidence to support the complaint that representatives were targeted on the number of GP-PEP meetings and this was linked to a reduction or removal of a pay increase. In that regard, the complainant attached an appraisal documents from two years, clearly showing that GP-PEP was used as a measurable parameter of performance and was in fact given a 15% weighting in one year. The complainant noted that the Panel had noted its ruling of no breach in the above and decided that a ruling of a breach of Clause 2, which was reserved as a sign of a particular censure, was not warranted in this instance and no breach was ruled. The complainant asked that in light of the additional information and the fact that Grünenthal had responded to the PMCPA's request for information in what could only be described as a dishonest manner by withholding information and falsely representing facts, that the Appeal Board reconsider a breach of Clause 2 in this instance.

The complainant stated that in light of the seriousness of the breaches he/she wanted to be kept informed of the actions which the PMCPA would take against Grünenthal and if any individual company representatives within Grünenthal would be held accountable. It was apparent that Grünenthal had not learnt any lessons from the ruling against it in 2013 and the complainant considered that this was something that should obviously be taken extremely seriously and trusted this would be done when deciding on appropriate sanctions.

COMMENTS FROM GRÜNENTHAL

1 Activity targets for representatives, Clause 15.4

Grünenthal submitted that at the outset of investigating this complaint, all calls recorded against individual health professionals in its CRM system were assessed to identify whether more than three calls had been logged against any individual health professional in a calendar year. As detailed above three representatives were identified to have registered more than three cold calls with the same health professional over a calendar year. This affected 15 health professionals (4-6 interactions were logged as cold calls). Grünenthal interviewed each representative (including one who had retired from the organisation), and as per its submission, each insisted that they had not conducted more than three cold calls with any health professional. As previously presented, the figures identified were therefore indicative of an error in call recording in the CRM system rather than inappropriate over calling on health professionals.

Grünenthal submitted that in response to the complainant's appeal, an additional review was conducted specific to the calls that the quoted representative logged against the named doctor in 2014, 2015 and 2016. The number of interactions (planned and completed) were four face-to-face calls in 2015, and there had been four face-to-face calls to date in 2016 (there were no recorded interactions against this health professional by the quoted representative in 2014). None of these calls were 'cold calls'.

2 GP-PEP, Clauses 18.1 and 23.1

Grünenthal submitted that a senior manager who was in place during the time periods referred to in

the complaint had confirmed that there had never been targets associated with a minimum number of prescriptions required by health professionals in order to be considered as a speaker. Formal working instructions had been in place since the programme was initiated as stated above, and no version had ever referred to a minimum number of patients or prescriptions required in order to commission a health professional as a speaker. Grünenthal continued to refute the allegation that the GP-PEP was an inducement to prescribe, contrary to the requirements of Clause 18.1, and in addition continued to maintain that engaging health professionals as speakers in relation to this programme was appropriate and consistent with the requirements of Clause 23.1. Without copies of the emails referred to by the complainant, any further information on who might have sent such emails, or any other further or better particulars in relation to this allegation, Grünenthal regretted that it was unable to investigate this any further.

Grünenthal submitted that with regard to the review of all speaker services in 2014, 2015 and 2016 as referred to above, it was exceedingly disappointed and embarrassed that its original response was not wholly complete. In response to the complainant's comments, Grünenthal reviewed all the speaker services provided by the named doctor speaker in the stated time period and found that he/she had spoken at a meeting in July 2015 but no contract could be found, either as an electronic version attached to the record in the CRM system, or as a hard copy. The status of the meeting in the CRM system was 'Cancelled' which indicated it had not gone ahead, therefore it was not included in its initial review. Attendees were however listed as having attended the meeting, and there were associated costs which indicated the meeting did take place (although no payment had been made to the named doctor).

Grünenthal submitted that it was feasible that a contract was signed but not received by head office for payment to be processed, however, the representative who commissioned this health professional to speak had now left the company and it was unable to verify whether or not he/she created an agreement and obtained a signature covering the services provided in advance of the commencement of services or not.

Grünenthal submitted that in light of the above, it further reviewed of all the contracts assessed as part of its original submission. Grünenthal provided the raw data and summaries as an enclosure. In summary, five speaker agreements were signed after the meeting took place in 2014, and four in 2015 (none for 2016). This differed to Grünenthal's original submission where it stated five agreements had been signed after meetings had taken place. The initial manual review of all contracts in preparation for Grünenthal's original submission was conducted by sales managers and the results sent to the internal investigating manager. Unfortunately, rather than using the drop-down options that had been installed in an Excel tracker to indicate where contracts had not been signed in advance of a meeting, there were four instances of 'colour coding' the line entries instead. No explanation had been provided to the investigating manager about the use of the colour coding and as such, the numbers for Grünenthal's submission were calculated using a filter based on the selection of the assigned drop-down options. The investigating manager regretted not identifying these anomalies and querying this when the data was collated.

Grünenthal submitted that neither electronic nor hard copy contracts could be located for four speakers in 2014 and two in 2015 (including the named doctor). It was not a requirement for colleagues to upload scanned copies of signed contracts in the CRM system until mid-2015, therefore if paperwork was lost in the post before this point, Grünenthal unfortunately did not have any back-up copies. Grünenthal identified this gap in its process in mid-2015 and copies of all signed agreements must now be attached to applicable records in the CRM system for reference in such an eventuality.

Grünenthal confirmed that the seven speakers for whom it could not locate signed contracts had not been paid for the services they provided as it processed payments against agreements submitted to finance. Grünenthal did not however have any evidence that it could share with the Appeal Board to confirm that there was a signed agreement in place to cover the services provided, or that they signed contracts before the services were provided. These contracts were not identified as being missing in the original review as the instructions provided to the sales managers asked that they identify using drop-down options in an Excel tracker whether agreements with speakers had been signed in advance of the meeting, on the day of the meeting, or after the meeting. A fourth option should have been offered to indicate where no contract could be located (hard copy or electronic), but this wasn't anticipated to be seen at the outset of the investigation.

Grünenthal apologised unreservedly for the error in its original submission in which it stated that only five speaker agreements were signed after meetings took place during 2014-2016, whereas in fact the figure was nine (five in 2014 and four in 2015).

Clause 9.1

Grünenthal provided the full performance review document provided by the complainant for 2013 which was easier to read than the scanned images provided (Grünenthal noted that this referred only to 2013 – Grünenthal had not received any images for two years as referred to by the complainant, only those that matched the 2013 appraisal).

Grünenthal submitted that the Non-short term incentive (STI) goal 'Annual A plan objectives and activities delivery e.g. GP PEP, KnEx etc. (C= 90% of objectives met) 15%' referred to the cycle plan created by the individual themselves. As per its response above, Grünenthal had a 'bottom-up' approach to planning activities as local representatives should know how best to grow their local business. They therefore devised their own local business plan which they were assessed

against. This might include planning and delivering speaker meetings in key areas, or might not – this was determined by the representative. There was not a company standard required for each representative with regards completing a company determined number of GP-PEP meetings, as local environments differed on the potential success of being able to run meetings of this nature; each representative decided whether this was a suitable and relevant objective based on their assessment of their local environment. The performance assessment provided described a weighting of 15% given to achieving at least 90% of what the representative said they would deliver, but this was in reference to all objectives and activities that comprised the cycle plan, not just delivering speaker meetings. The representative's salary increase was not purely dependent on his/her achievement of the Non-STI Goals and core activities as documented in the 2013 appraisal form. In addition, the completion of all duties as specified in his/her job description and the individual's behaviours and approach were also considered when deciding on a salary increase. The calculation of an overall rating for representatives was determined by the line manager, comprising of their performance against core activities, non-STI goals, job requirements and behaviours. The examples of the assessment of three different representatives in 2013 were provided.

Clause 2

Grünenthal submitted that it had provided a complete and factually accurate submission in response to the allegation that representatives were targeted on the number of GP-PEP meetings, therefore the complainant's accusation of false representation was incorrect. Grünenthal disputed the alleged breach of Clause 2.

FINAL COMMENTS FROM THE COMPLAINANT

1 Activity targets for representatives, Clause 15.4

The complainant stated that his/her appeal was not about the number of times a representative 'cold called/spec called' a health professional and he/she had not suggested that this was the case. The appeal, actually questioned the fact that Grünenthal used cycle plans as a targeted measure for representatives on which sales bonus was or was not payable and that within those plans representatives were expected to plan more than one call per customer per quarter. The complainant submitted that he/she had stated that Grünenthal's CRM system which held the cycle plans showing calls planned on a given [health] professional over the period of a quarter would show that representatives were planning prior to a quarter to visit a health professional more times than was allowable within the Code. The complainant noted that he/she had suggested that the CRM system should have been interrogated and provided details of a cycle plan which would show a named customer whom a representative was planning to see 13 times, later reduced to 11 times in a quarter. Representatives were instructed to always change the default option to requested a return visit.

The complainant alleged that no representative could state before the beginning of a three month period that a health professional would 'request a return visit' 11 times within the next three months. To plan that level of activity and then to achieve it would suggest some inaccuracies either in the way in which these calls were recorded and a definitive plan to act in breach of the Code.

The complainant alleged that the part of the system that required interrogation was the cycle plans and not the calls logged. The complainant also suggested that as Grünenthal archived all of its CRM system data at the end of each quarter, that the archived data was checked rather than the current live data set.

2 GP-PEP, Clauses 18.1 and 23.1

The complainant alleged that as Grünenthal had chosen to ignore the details in his/her complaint it had failed to respond to the complaint accurately. Grünenthal had stated that 'working instructions' had been in place and that these had never stated a minimum requirement for prescribing by health professionals used as speakers. The complainant noted that Grünenthal had only provided the working instructions as its evidence in appeal but that although figures were not stated in these documents, Grünenthal had been very careful in only stating these figures in presentations at company meetings and emails. The original PEP presentation was made by several people at a company meeting. The complainant stated that with regards to the meeting at the named hotel in July 2015 where the named doctor was the speaker, he/she could categorically state, as he/she was the representative who carried out that meeting, that the meeting did take place and that the hotel was paid £400 by Grünenthal for catering costs. With this in mind the complainant failed to understand how Grünenthal could suggest that it thought that the meeting had been cancelled. The complainant stated that when he/she left Grünenthal the meeting was not marked in the system as cancelled. Again the complainant suggested that the status had been amended within the system since he/she had left the company and would again suggest that archive files be accessed in order to prove that this was the case.

Grünenthal stated that the representative responsible (the complainant) had left the company and it had been unable to verify whether a contract was signed for the services of the named doctor speaker. The complainant was extremely shocked and disappointed to read this comment as Grünenthal had his/her contact details and despite still being in contact with him/her until early 2016, Grünenthal had made absolutely no attempt to contact him/her to verify this information.

Clause 9.1

Firstly the complainant stated that he/she was shocked that Grünenthal, rather than accept the copy of the appraisal document which had been amended to not reveal his/her identity found the time to trawl through its system in order to identify the owner.

The complainant considered that Grünenthal's subsequent inclusion of the document was in some way made in order to intimidate.

The complainant noted the comments made by Grünenthal in its defence were at best ill-informed and at worst a poor attempt at deception. Grünenthal stated that, 'that the Non-STI goal 'Annual A Plan objectives and activities delivery eg GP PEP, KnEx etc 15%' referred to the cycle plan created by the individuals.

The complainant referred the Appeal Board to the actual document sent by Grünenthal. There were 6 Non STI goals listed as measures, each with a percentage weighting against them. The first of these referred to 'A Plan activity Cycle plan delivery x 4 (100% = call volume)' and this had a weighting of 15%. The second Non-STI goal however, specifically stated 'eg GP PEP, KnEx etc' and this too had a weighting of 15%. The complainant was disappointed that Grünenthal suggested that it had set two separate Non-STI goals on a performance review document that were identical in an attempt to defend its actions.

Clause 2

Despite Grünenthal's assurances that it had provided complete and factual information the complainant alleged that this was not the case. Grünenthal had either deliberately or through incompetence failed to respond to the actual points made in the appeal, instead supplying irrelevant information and failing to provide the suggested information.

From the information that Grünenthal had supplied the complainant suggested that it had taken reports from the post archived CRM data which was not representative of information which was originally submitted. Grünenthal had not tried to contact representatives about speaker contracts and instead chose to state that the representatives were not contactable. The complainant alleged this was a blatant lie. Grünenthal had deliberately misrepresented data from the PDP, again either through incompetence or as a deliberate attempt to avoid the truth.

The complainant alleged that Grünenthal had for some time a culture ensuring that call reporting within the CRM system was made in such a way as to fit in with requirements of the Code. With all of this in mind the complainant alleged that Grünenthal's actions had brought the industry in disrepute.

APPEAL BOARD RULING

The Appeal Board was concerned about this case noting the Panel's rulings of breaches of Clauses 15.4, 29, 9.1 and 2 (Point 1) and Clause 9.1 (Point 2) had been accepted by Grünenthal. The company referred to changes in its systems instigated as a result of this case.

1 Activity targets for representatives

The Appeal Board noted from the supplementary information to Clause 15.4 that the number of cold calls made on a doctor or other prescriber by a representative each year should not normally exceed three on average; the representatives from Grünenthal submitted that the company set 3 cold calls per year as an absolute which must not be exceeded. The Appeal Board noted that Grünenthal had some data to show that three of its representatives had called upon individual health professionals more than three times in a year. Upon investigation Grünenthal submitted that each representative insisted that they had recorded the calls incorrectly in the CRM system and had not cold called more than 3 times on an individual health professional.

The Appeal Board noted that in his/her appeal the complainant had alleged that during 2015 a named representative originally planned to call on a named doctor 13 times in one quarter which was subsequently reduced to 11 by the line manager. The Appeal Board noted that Grünenthal had conducted an additional review specific to the calls logged by the representative against the doctor in 2014, 2015 and 2016 and none of these were cold calls. Grünenthal submitted that the health professional in question was one of its speakers and so some of the visits to him/her would be by the local representative to get speaker agreements signed.

The Appeal Board considered it was unusual for three representatives to make the same error in call recording such that calls which were not cold calls were nonetheless recorded as such. Although the Appeal Board was concerned about these errors it noted that the burden was on the complainant to prove his/her complaint on the balance of probabilities. The Appeal Board considered that, on balance, there was insufficient robust evidence to show that representatives had over called on health professionals as alleged and it upheld the Panel's ruling of no breach of Clause 15.4. The appeal on that point was unsuccessful.

2 GP-PEP

The Appeal Board noted that in its response to the complaint, Grünenthal had submitted that five speaker contracts had been signed after the relevant event took place. Following the appeal Grünenthal subsequently found this to be incorrect, and its review identified nine in total (five in 2014, and four in 2015). In addition to this, Grünenthal submitted that no contracts (electronic or hard copy) could be found for four speakers in 2014, and two in 2015 (including that of a doctor named by the complainant). The Appeal Board was concerned about this omission. The Appeal Board noted from the representatives from Grünenthal that as there were no contracts for the six speakers, none had been paid.

The Appeal Board noted from the company representatives at the appeal that the meeting involving the named doctor, as referred to by the complainant in his/her appeal, had in all likelihood gone ahead as its investigation had revealed that there were expenses attached to it. Grünenthal's investigation had also revealed that that the CRM status of the meeting had been marked as cancelled

by the line manager of the representative who organised the event.

The Appeal Board noted that Clause 23.1 stated that before a consultant provided a service a written contract or agreement, which specified the nature of the services to be provided and the basis for payment of those services, had to be signed in advance. The Appeal Board noted Grünenthal's submission that neither electronic nor hard copy contracts could be located for four speakers in 2014 and two in 2015. Given the lack of evidence of an agreement in advance for these six speakers the Appeal Board ruled a breach of Clause 23.1. The appeal on that point was successful.

The Appeal Board noted that the GP-PEP Speaker Justification form (GB-MK-908-0003-T13-AA) stated that in order to decide if a health professional could be a GP-PEP speaker one of the questions to be asked was 'Does the healthcare professional have sufficient experience prescribing Palexia SR and/or Versatis for them to be considered a credible product speaker at a Grünenthal GP-PEP meeting?'. The Appeal Board queried how representatives would interpret 'sufficient' but nonetheless considered that it was reasonable for a company to establish if a speaker on a particular medicine was familiar with it. The complainant referred to emails which indicated that consultants should have prescribed the medicine to 10 patients, but did not have copies of them. In response to questioning Grünenthal had been unable to find the emails in question. The Appeal Board considered that it had no evidence to show that Grünenthal required health professionals to prescribe its medicines for a minimum number of patients before being selected as speakers as alleged and thus it upheld the Panel's ruling of no breach of Clause 18.1. The appeal on that point was unsuccessful.

The Appeal Board noted Grünenthal's submission that it had never set representatives a target number of meetings to hold per quarter since GP-PEP was established in 2012; the number of meetings completed by a representative did not affect his/her bonus or annual pay rise as alleged. The Appeal Board noted that the onus was on the complainant to prove his/her complaint on the balance of probabilities, and as it considered that there was no evidence in this regard it upheld the Panel's ruling of no breach of Clause 9.1. The appeal on that point was unsuccessful.

The Appeal Board noted its rulings above and decided that a ruling of Clause 2, which was reserved as a sign of particular censure, was not warranted in this instance and it upheld the Panel's ruling of no breach in that regard. The appeal on that point was unsuccessful.

Complaint received **23 February 2016**

Case completed **16 August 2016**
