CASE AUTH/2852/6/16 *NO BREACH OF THE CODE*

EX-EMPLOYEE v GRÜNENTHAL

Medical science liaisons' working practices

An anonymous, contactable ex-employee complained about the working arrangements for medical science liaisons (MSLs) at Grünenthal.

The complainant stated that he/she had always sought help and guidance from senior leadership and compliance to ensure that his/her day-to-day work was conducted according to Grünenthal's stance that compliance was at the core of its culture. Unfortunately as commercial pressures mounted in 2015, head office and field-based medical affairs colleagues were asked to take on tasks which were not within the scope of their respective roles.

The complainant decided to complain to protect future Grünenthal MSLs/scientific advisors or medical information scientists, from being used in a non-compliant manner, in the absence of clear briefing documents and guidance which was verbal rather than consistent, transparent and formally documented.

The complainant alleged that Grünenthal used a reactive, non-promotional, field-based MSL team in a 100% proactive manner to target an inappropriate group of health professionals who did not primarily treat pain (Grünenthal's main therapy area). The company set 100% customer-facing time targets, with the aim of facilitating discussions with oncologists and palliative care specialists, to disguise the promotion of Palexia Oral Solution (tapentadol).

At the end of the April 2015 the MSLs were informed that they would be expected to spend every day seeing customers in the field and could no longer work reactively. No exceptions were to be made and the line was 'every day is a field day'.

Despite disagreement from the MSLs, an email was sent to the team (copy provided) with a target list of palliative care and oncology health professionals. Some additional verbal instructions were also provided. The new way of working meant that MSLs had to proactively target an agreed list of 100 customers every day with a particular opportunity for Palexia Oral Solution which was not doing very well since launch. The MSLs protested that Grünenthal pain products were not licensed in palliative care so they would effectively be conducting disguised promotion of an off-licence indication.

The MSLs were dissatisfied with this new proactive, disguised promotion to an off-licence customer base, and so not all followed the instructions at first. The MSLs thus received another email asking them to keep their calendars up-to-date with where they would proactively be each day. This caused stress and resentment amongst the MSLs as they were approaching hospital oncology and palliative care departments to proactively speak to health professionals about a pain medicine not licensed in oncology and palliative care; the trials for Palexia were in osteoarthritis and lower back pain.

The complainant stated that Grünenthal demonstrated its seriousness with the 100% proactive approach by asking each MSL to record whom they had seen and the output of those interactions. Some MSLs stated that the approach was demoralising and that health professionals refused to see them. Additionally, at monthly team meetings, MSLs had to share what they had done each month which was disguised on the agenda under 'Any other business'.

The complainant alleged that Grünenthal wanted the salesforce and market access teams to focus on the main brands ie Palexia SR, Palexia tablets, and Versatis, and thought of an underhand way of disguising the promotion of the relatively new Palexia Oral Solution via the MSL team so the salesforce would not be distracted from the core brands.

The detailed response from Grünenthal is given below.

The Panel noted the complainant had provided copies of two short emails from his/her manager which provided the target list of health professionals, with instructions as to its use, and a reminder to update calendars respectively. The complainant subsequently provided two lists of health professionals which had been entitled by hand 'unlicensed customer group, palliative care and oncology' and 'target list' respectively. The Panel noted that the Constitution and Procedure clearly stated that a complainant had the burden of proving his/her complaint on the balance of probabilities.

The first email provided by the complainant was sent by the head of MSLs and was not dated. The MSLs were instructed to look at the top 100 people from their list, check with colleagues if they were already doing business with those individuals and determine whether seeing an individual would have a negative impact. Once satisfactory, the lists could be finalised and would form part of the end of year assessments. The second email headed 'Every day is a field day' was dated and sent by the head of MSLs who asked those MSLs who had not already done so to update their calendars with where they would be in the field given Grünenthal's new focus. The Panel noted that whilst neither email instructed MSLs to discuss products it appeared that the MSLs would be assessed on the percentage of health professionals seen on their 'proactive' target lists. This appeared to be contrary to the Medical Science Liaison Policy (effective from December 2015) which stated that remuneration for MSLs must not be linked to number of visits, meetings etc. but a bonus scheme linked to the percentage of enquiries or visit *requests* (emphasis added) completed might be acceptable.

In the Panel's view it was thus not necessarily unacceptable for MSLs to be in the field every

day. The Panel noted Grünenthal's submission that the role of the MSLs was non-promotional in action and intent. However, the Panel noted that the MSL job descriptions relevant at the time were identical and stated at the outset that the position provided support to the medical department in order to achieve the company's goals. The overall purpose of the role included, *inter alia*, to introduce and build new product awareness and facilitate formulary submissions. MSLs were required to identify and develop strong sustainable relationships with external customers to deliver the opportunity to execute product strategy. The Panel noted that the working instruction for the MSLs (which was in place over the first six months in question (June – November 2015) and the Medical Science Liaison Policy which succeeded it, both allowed MSLs to proactively introduce their role. In that regard the MSL introductory leavepiece listed a number of services available including, *inter alia*, 'information on effective and appropriate use of Grünenthal pain products'. The Panel queried whether requests for information received in response to the leavepiece/ introductory visit were, in effect, solicited and so responses to them would not be exempt from the definition of promotion. Overall, the Panel considered that, given the broad definition of promotion in the Code, elements of the MSL role were promotional. In that regard, the MSLs were thus covered by the requirements in the Code for representatives who were defined in the Code as calling on members of health professionals and other relevant decision makers in relation to the promotion of medicines.

The Panel noted Grünenthal's submission that before the target list was emailed there were verbal discussions with the MSL team in preparation of the release of the list (objectives, actions required, measures that would be used, inclusion in assessment priorities). The Panel was concerned that Grünenthal had not provided any written briefing document to accompany the target list particularly as this was a new way of working for the MSLs. The Panel noted that Grünenthal confirmed that there were never any instructions provided to 'steer conversation' towards any of its products. The Panel also noted that in the first 6 months of setting the MSLs a new way of working (June-December 2015), only two team meetings were held; one in June to discuss target lists and priorities and one in October for which there was no agenda. Meetings in 2016 (January – June) were held in every month but February. No minutes were available from any meeting. The Panel noted Grünenthal's submission that future meetings would be documented. The Panel considered that the lack of any record of the MSL team discussions was regrettable. It meant that the company had no evidence to support its submission that MSLs were not instructed to steer the conversation towards Palexia Oral Solution or any of Grünenthal's products or that they were not otherwise briefed in a way that would advocate, either directly or indirectly, a course of action which would be likely to lead to a breach of the Code. The Panel noted that the complainant bore the burden of proof to establish that, on the balance of probabilities, MSLs were so briefed. The Panel noted its comment above that the emails provided by the complainant did not instruct MSLs to discuss products. In the circumstances, no breach of the Code was ruled.

The Panel noted Grünenthal's submission that nothing was ever raised directly from any MSL or in association with this complaint to suggest that a health professional had been inconvenienced by an MSL, nor that arrangements at any particular establishment were not observed. On the basis of the evidence before it the Panel ruled no breach of the Code.

The Panel considered that there was no evidence before it to suggest that the MSLs had promoted any medicine, for off-licence use or otherwise, as alleged and therefore ruled no breach of the Code. There was thus no evidence to suggest that there had been disguised promotion. No breach of the Code was ruled.

The Panel noted Grünenthal's submission that it had prioritised the introduction of the MSL role to oncologists and palliative care specialists as the number of enquiries received from them demonstrated their need for information. A review of requests for information logged in the medical information system identified 200 queries from health professionals that flagged positive for the words 'oncology' 'palliative' 'cancer' between 17 May 2013 and 18 May 2015. The Panel considered that given these figures oncologists and palliative care health professionals' need for, or interest in information about Grünenthal's products could reasonably be assumed and no breach of the Code was ruled.

The Panel did not consider that the complainant had shown that on the balance of probabilities the MSLs or Grünenthal had failed to maintain high standards. No breaches of the Code were ruled. The Panel noted its rulings above and consequently ruled no breach of Clause 2.

An anonymous, contactable ex-employee complained about the working arrangements for medical science liaisons (MSLs) at Grünenthal Ltd.

COMPLAINT

The complainant stated that he/she had always sought help and guidance from senior leadership and compliance to ensure that his/her day-to-day work was conducted in the spirit of the company's acclaimed slogan that compliance was at the core of its culture. Unfortunately as commercial pressures mounted in 2015, both head office and field-based medical affairs colleagues were asked to take on tasks which were not within the scope of their respective roles.

The complainant decided to complain to protect future members of Grünenthal medical, be it MSLs/ scientific advisors or medical information scientists, from being used in a non-compliant manner, in the absence of clear briefing documents and guidance which was verbal rather than consistent, transparent and formally documented.

The complainant alleged that Grünenthal used a reactive, non-promotional, field-based MSL team in a 100% proactive manner to target an inappropriate group of health professionals who did not primarily treat pain (the therapy area Grünenthal products fell within). The company set 100% customer-facing time targets, with the aim of getting the team to facilitate discussions with oncologists and palliative care health professionals, to disguise the promotion of Palexia Oral Solution (tapentadol).

The complainant explained that at the end of the April 2015 company conference the MSLs were informed by their manager that there would be a new way of working in that they would be expected to spend every day seeing customers in the field and could no longer work as a reactive function. No exceptions were to be made and the line was 'every day is a field day'. Even administrative days had to be requested and were granted at the manager's discretion. The new way of working meant that MSLs had to be out proactively targeting a list of customers every day.

Despite disagreement from the MSLs, it was made clear that there was no room for discussion, and that commercial pressures meant this had to happen. Soon after this announcement an email was sent to the MSL team with an attached target list of palliative care and oncology health professionals. Some additional verbal instructions were also provided.

The complainant stated that MSLs were to proactively pursue an agreed target list of 100 customers and discuss products, with a particular opportunity for Palexia Oral Solution which was not doing very well since launch. The team was not to disrupt existing customers ie those already prescribing Grünenthal's products, as this could be bad for business. In short, the MSLs were to introduce themselves to health professionals and try to steer the conversation to discuss product. The MSLs protested that Grünenthal pain products were not licensed in palliative care, so they would effectively be conducting disguised promotion of an off-licence indication.

The complainant stated that the MSLs considered this to be non-compliant for a reactive MSL function because:

1 All of the activity (100%) would become proactive with 100% field time in that manner, and they were meant to serve as a reactive function.

2 Steering the conversation to the Palexia Oral Solution was non-compliant, and they would be in breach of the Code under disguised promotion. The MSL team learnt very quickly with frowny looks from doctors that the focus of oncology/ haematology health professionals was on chemotherapy. Often colleagues were told by oncology health professionals that, as a pain specialist company, Grünenthal was seeing the wrong people.

3 Each MSL had to meet a target which would form part of the end of year assessments, which were all about bonus and a salary increase.

The MSL team was dissatisfied with this new proactive, disguised promotion to an off-licence customer base, and so not all followed the instructions in the first few days. The MSLs thus received another email from the MSL manager asking them to keep their calendars up-to-date with where they would proactively be each day. This caused stress and resentment amongst the MSLs as they were approaching hospital oncology and palliative care departments to proactively speak to health professionals about a pain medicine not licensed in oncology and palliative care; the trials for Palexia were in osteoarthritis and lower back pain.

The complainant stated that Grünenthal demonstrated its seriousness with the 100% proactive approach by asking each MSL to record whom they had seen on a spreadsheet and to explain what the output of those interactions were at monthly meetings. Some MSLs stated that the approach was demoralising and that oncologists and palliative care health professionals were shutting doors in their faces. Additionally at monthly team meetings, MSLs had to share what they had done each month which was disguised on the agenda under 'Any other business'.

The complainant alleged that Grünenthal wanted the salesforce and market access teams to focus on the main brands ie Palexia SR, Palexia tablets, and Versatis, and thought of an underhand way of disguising the promotion of the relatively new Palexia Oral Solution via the MSL team so the salesforce would not be distracted from the core brands.

The complainant subsequently provided two lists of health professionals which had been entitled by hand 'unlicensed customer group, palliative care and oncology' and 'target list' respectively.

When writing to Grünenthal, the Authority asked it to consider the requirements of Clauses 2, 3.2, 9.1, 11.1, 12.1, 15.2, 15.4 and 15.9 of the Code.

RESPONSE

Grünenthal explained that its team of field-based MSLs were all either PhD scientists, or pharmacists. Copies of the MSL job descriptions, effective August 2013 – June 2015 and June 2015 to date, were provided.

Grünenthal submitted that the MSL role was non-promotional in action and intent. Further to the MSL job description, this was supported by the Medical Science Liaison Policy (the current version effective from 1 December 2015 and the previous work instruction which it replaced (effective from 14 February 2013 – November 2015) were provided). The role provided a clinical/scientific service to health professionals to facilitate optimal healthcare provision for patients. This could be achieved through either reactive contact in response to unsolicited, specific, individual requests from health professionals or via proactive contact by the MSLs.

Reactive contact was in response to unsolicited specific enquiries or requests for information (RFIs)

that the company received from health professionals. RFIs might be about one of Grünenthal's products (within and outwith product licence) or a disease area in which it operated. The majority of RFIs were managed by the head office medical information department but if a face-to-face visit was requested, this was allocated to the local MSL.

The current Medical Science Liaison Policy described the following proactive activities in which MSLs might engage:

- 'MSL role introduction
- Matters relating to patient safety, for example to support a risk mitigation activity or further to a request from drug safety (ie to follow up adverse drug reaction reports)
- Identification of investigators for clinical trials, feasibility work of sites for clinical trials
- Legitimate exchange of medical and scientific information during the development of a medicine
- Medical education or clinical disease area discussions. NB There must be no reference either direct or indirect to specific medicines; however, general reference to Grünenthal's interest in the disease area is acceptable
- Training of internal staff.'

The Medical Science Liaison Policy specifically stated that 'Any proactive activity outside of those described above, particularly in relation to information about a specific medicine, could be deemed promotional and are not acceptable or appropriate activities for MSLs to perform'.

Other activities the MSL team engaged in included visits with health professionals that were requested return visits (where following a RFI the health professional requested a subsequent meeting with the MSL), training of external speakers, internal employee training, support of medical and educational goods and services (MEGs) and involvement in special projects. In addition, the MSL team was represented on numerous internal cross-functional groups, eg compliance champion team, field marketing group champion.

The MSL team had a number of objectives, referred to internally as 'priorities'. These were set and reviewed annually as part of the individual appraisal process with each MSL. Achievement or failure of priorities influenced salary and bonus. Details of the five priorities that were set for the MSL team in 2015, all of which were equally weighted was provided and included a range of customer-facing and non customer-facing activities; promoting the MSL role to health professionals was one of them. The review of priorities was a frequent agenda item for the monthly face-to-face MSL team meetings (examples of six MSL team meeting agendas from 2015 and 2016 were provided).

The difference between proactive engagement of health professionals by MSLs and representatives was that representatives proactively sought to promote the use of Grünenthal's product portfolio, whereas MSLs were limited to the activities described and did not proactively contact health professionals in order to discuss medicines. Grünenthal confirmed that the email supplied by the complainant was sent to the MSL team in June 2015.

Since 2014 the MSLs had been required to proactively introduce their role to health professionals. Initially this activity focussed on pharmacists as they were not routinely targeted by other company staff. The management of pain was often polypharmacy and therefore pharmacists submitted a large proportion of RFIs. Approaching a group of health professionals not otherwise engaged by the business prevented any blurring between the objectives of promotional and non-promotional interactions with the same individuals so the differences between representatives and MSLs should have been obvious for the health professionals, in line with the PMCPA guidance on Clause 3.

A leavepiece which introduced the MSL role to health professionals was first used in April 2014 and had the objective of 'Leaflet to raise awareness and understanding of the MSL role, these will be given out by the MSL at congresses, or when meeting healthcare professionals, to introduce the role of the MSL'. A copy of the leavepiece was provided.

Following a company conference in May 2015 (not April 2015 as stated by the complainant), the MSLs widened the group of health professionals they introduced their role to, to include oncologists and palliative care clinicians. This decision was borne from the capacity for MSLs to increase their customer-facing activities, and focussed on oncologists and palliative care clinicians because both groups prescribed analgesics to patients in often clinically complicated scenarios, and the demand for RFIs received from both groups. The scope of the MSL role remained unchanged and they continued to operate with all health professionals in a strictly non-promotional manner.

Grünenthal noted the complainant's concern that 'every day is a field day'. The context behind this was that whilst the MSL team was non-promotional, it was field-based and therefore when diaries were empty, each team member should approach work proactively, including liaising with health professionals to introduce the MSL role. In reality, company commitments, eg internal meetings, training sessions, conferences, etc impacted on individuals' ability to be field-based for 100% of their time so this was never realistically achieved week on week; nevertheless, there was a drive to prioritise customer-facing time.

The MSL team was never instructed that 100% of its activities were to be proactive; the five equally weighted priorities across a range of different activities, included the proactive introduction of their role. If there was an expectation to spend 100% of their time proactively introducing their role, they would not have been able to meet their other priorities.

A report on medical information enquiries assigned to and closed by MSLs between Grünenthal's company conference in 2015 (22 May 2015), and

22 June 2016 (when the investigation into this complaint commenced) indicated that over 180 RFIs were assigned to the MSL team by the medical information service (this did not include enquiries that were assigned to an MSL but the health professional did not respond or no longer wanted a visit and the RFI was closed by medical information). If the MSLs had been expected to spend 100% of their time proactively engaging health professionals, they would not have been able to fulfil these RFIs.

The complainant alleged that oncologists and palliative care clinicians were inappropriate groups to work with because they did not primarily treat pain, however pain was a symptom common to many disease states, particularly cancer and terminal conditions, and therefore it was relevant to all clinicians; few clinicians primarily just managed pain. Furthermore, clinicians that managed cancer patients, even if they did not routinely initiate pain management themselves (eg oncologists), would treat patients who were suffering pain and/or being treated with analgesics. An awareness of analgesics that might be used in cancer patients, and which could be used concurrently with other medicines that were used in the treatment of cancer, was therefore important.

A review of RFIs logged between 17 May 2013 and 18 May 2015 (ie the two years preceding the 2015 company conference) identified over 200 that flagged positive for the words 'oncology' 'palliative' and 'cancer' (most were logged by physicians, or by pharmacists). Of the queries, nearly 50 were allocated to, responded to and closed down by MSLs. It could thus be reasonably assumed that oncologists and palliative care clinicians might have queries in relation to Grünenthal medicines and might be interested in the services provided by the MSL team. This was why it was decided that MSLs should widen the group of health professionals to whom the role was introduced to include oncologists and palliative care specialists.

Given the above, Grünenthal disputed the alleged a breach of Clause 11.1 as oncologists and palliative care specialists could reasonably be assumed to be interested in pain management.

Grünenthal stated that its list of oncologists and palliative care specialists was compiled based on clinical commissioning group (CCG) patient population size in each MSL's territory using data from an external data provider. The MSL team was sent the list as per the email provided by the complainant, and asked to liaise with cross-functional colleagues to ensure that for each individual there was no other engagement with Grünenthal eg an existing relationship with the company, an ongoing project, a known blockage to pharmaceutical companies or any other reasons why it would be inappropriate for the MSL to call. This ensured health professional interactions with cross-functional colleagues were kept separate. If there was an existing relationship or other challenge, the identified individuals were removed from the list and replaced with others from the master list. The final group of oncologists and palliative care specialists was therefore intentionally not also called upon by promotional teams to prevent clouding of promotional interactions with Grünenthal with non-promotional interactions – different activities were to be kept separate. Once the list was finalised, each MSL began to initiate proactive activities with the top 100, moving into the list of subsequent individuals as needed.

In engaging oncologists and palliative care specialists, the MSLs were instructed to approach them in the same manner as with their proactive engagements with pharmacists, ie to introduce the MSL role using the MSL introductory leavepiece as support.

Grünenthal confirmed that the team had never been instructed to 'steer conversation' towards any of Grünenthal's products. Whilst the wording of the email provided by the complainant implied prior conversations took place about the list, unfortunately no written briefings or supporting evidence (eg meeting minutes) could be provided. Grünenthal understood that there was a failing in the clarity in the email as a standalone briefing document, that this was not good business practice and it fell below the standards expected. It had also been made clear that minutes must be taken during future MSL team meetings and these must be centrally stored along with written agendas circulated in advance of meetings.

Before the email was sent there were verbal discussions with the MSL team in preparation of the release of the list (objectives, actions required, measures that would be used, inclusion in assessment priorities). Grünenthal understood that the wording of the email was ambiguous, and in the absence of other written briefing there might have been confusion as to some of the language used, however as the activity was limited to MSL activities, it did not believe Clause 15.9 was relevant as that clause related to the briefing of representatives. The head of MSLs acknowledged that there should have been a more detailed written briefing, and had committed to ensure more structured written MSL briefing documents and meeting minutes in future. Grünenthal was disappointed that it was unable to provide more substantive evidence, however it confirmed that the MSLs were currently guided in their behaviour by the Medical Science Liaison Policy and used the MSL leavepiece to proactively introduce their role to health professionals.

Grünenthal submitted that it had contacted all members of the MSL team in role in 2015, when the list was distributed but who had now left the company, to gauge from them their understanding of the objective of the activity at issue. Whilst all were willing to be contacted, none were available within the timelines stipulated for providing the response to this complaint.

Grünenthal stated the complainant's reference to 'frowny looks from doctors' was never raised directly with the manager by any MSL or at any MSL team meeting. No evidence had therefore been provided to Grünenthal either directly from any MSL or in association with this complaint to suggest that any health professional was ever inconvenienced by an MSL, nor that arrangements at any particular establishment were not observed. Further, as the

MSL role was non-promotional and did not meet the definition of 'representative' as stated in Clause 1.7, the company submitted that Clauses 15.2 and 15.4 were not applicable with regard to the MSLs and so Grünenthal denied any breach of these clauses.

The complainant alleged that the MSLs were told their focus when working with oncologists and palliative care specialists was for the disguised promotion of Palexia Oral Solution in response to commercial pressures ('introduce yourself and try to steer the conversation to discuss product'). Grünenthal strongly refuted any allegation that MSLs were instructed to steer conversations with health professionals to discuss any of Grünenthal's products.

Grünenthal noted that Palexia Oral Solution was added to the UK Palexia portfolio in April 2014. It was not a significant product for the UK as it was clinically equivalent to Palexia film coated tablets rather than Palexia SR (slow release); there had been no additional company investment or any commercial incentives for its promotion. The complainant did not accurately recall the key strategic messages from the company conference in May 2015 if he/she truly believed the focus for the UK business was Palexia Oral Solution at that time.

In response to this complaint, Grünenthal reviewed RFIs logged and confirmed that from 1 May 2014 to 7 July 2016, just over 100 requests were logged with the words 'oral solution' or 'os'. Nearly 30 requests were responded to by MSLs. The basic reporting and search functionalities of the logging system meant that some enquiries about Palexia Oral Solution might have been missed, and others included that were not about the product (eg if requesting Palexia formulary information, the requestor might request that information was not provided on Palexia Oral Solution). There was therefore not much interest in Palexia Oral Solution information and few MSL calls logged about the product.

Grünenthal submitted that a review of a sample of calls logged in the company's customer relationship management (CRM) system as 'Introduction of MSL role' revealed no recorded discussions of Palexia Oral Solution or any other Grünenthal product in a proactive MSL call, therefore no evidence existed that there was any disguised promotion. Copies of 6 call notes were provided.

Given the above, Grünenthal strongly refuted the alleged disguised promotion of Palexia Oral Solution (or any other Grünenthal product) (Clause 12.1).

Grünenthal noted the complainant's reference to 'a pain medicine not licensed in oncology or palliative care' and that 'MSLs protested that Grünenthal pain products were not licensed in palliative care … so they would effectively be conducting disguised promotion of an off-licence indication'. Grünenthal reiterated that product promotion was not part of the MSL role, however Palexia could be prescribed, within licence, to treat pain in cancer patients. Palexia tablets and Palexia Oral Solution were licensed for 'the relief of moderate to severe acute pain in adults, which can be adequately managed only with opioid analgesics'; Palexia SR was licensed for 'the management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics'. Similarly, classical opioids such as morphine sulphate and oxycodone were indicated for 'severe pain' and not according to the underlying cause of the pain.

As stated above, the review of a sample of proactive call notes in the CRM system did not identify any proactive MSL calls during which product was discussed. Without any evidence to the contrary, Grünenthal therefore denied the off-licence promotion (Clause 3.2) of any product as alleged by the complainant.

Grünenthal stated that some of the MSLs themselves decided to modify the spreadsheet referred to by the complainant to create a tracker so they could monitor their own coverage of the list however, they were never asked to include any outputs of discussions as alleged.

There was no drive from the company to use this spreadsheet to record interactions, however attainment was measured on the basis of MSL self-reporting (by the spreadsheet when used by individuals, and other data sources). Details were provided of the coverage of the oncologist/palliative care list at the end of the year to be 100% achievement (internal priority rating = Performing). Grünenthal provided examples of the trackers used by two MSLs.

Although the priority was set with these measures during 2015 there was a high turnover within the MSL team which meant individuals had covered additional territories. In the end, this priority was not assessed according to the parameters set; examples were provided.

The use of a tracker did not replace entry of interactions with health professionals in the company CRM system and when responding to a RFI. No evidence was identified in the sample of call notes reviewed during the investigation that Grünenthal products were discussed during these introductory calls. Examples were seen of RFIs being submitted as RFI during the interaction and were logged as per the defined internal process.

Agendas for each of the MSL team meetings conducted in 2015 and 2016 were provided. The agendas were circulated in advance of meetings with input from the whole team. Grünenthal noted the following regarding MSL team meetings:

- June 2015: 'Target list and priorities' was an agenda item for the meeting which immediately followed the 2015 company conference.
- For the rest of the year, apart from October, there were no meetings for a variety of reasons. The agenda for the October meeting could not be found.
- January 2016: 'ED and MyView' ('ED' stands for Employee Dialogue, and MyView is the internal system priorities are logged within)
- February 2016: combined medical department meeting so no MSL team agenda

- March 2016: 'Change Pain and MSL Introductions'
- April 2016: 'Priorities 2016'
- May 2016: 'MSL introductions'
- June 2016: 'Priorities 2016'.

Minutes were not available for the meetings. As noted above, Grünenthal recognised that failing to take minutes was unfortunate and all future meetings would be appropriately documented.

A senior Grünenthal manager, who had recently left the company, had no recollection that any MSL expressed concern about proactive engagement with health professionals, the appropriateness of oncologists or palliative care specialists, or any fear of disguised promotion.

Grünenthal submitted that Compliance had led a group of cross-functional compliance champions who met every 6 to 8 weeks to discuss compliance-related topics and projects. There had always been an MSL team member in this group. A review of emails received from, and sent to the MSL team in 2015 and 2016 showed no queries that could be identified that were not responded to. No emails referred to the challenges described within the complaint and there was no recollection of verbal conversations related to these topics either. Compliance was consulted regarding proactive interactions with health professionals early in 2014, ahead of commencement of this activity; however this was led by two senior managers including the head of MSLs. Advice was provided that it was acceptable to proactively introduce the role of the MSL to health professionals provided that no product was discussed in such meetings.

A communication was written by a manager regarding the introduction of the MSL role to health professionals which was disseminated to commercial field managers. The wording of the communication was provided.

Grünenthal submitted that as it did not consider there were any breaches of the Code as above, the activity at issue did not fail to maintain high standards and thus was not in breach of Clause 9.1. The activity did not reduce confidence in the industry or bring the industry in to disrepute and was not in breach of Clause 2.

Grünenthal stated that its commitment to ensuring compliance was at the core of its culture was driven by the senior management team, the general manager, and by all line managers. This was clearly conveyed to all new employees when they commenced employment and continued during their employ. The tone with which the internal slogan was referred to by the complainant suggested that the company commitment to compliance was not genuine or sincere. Grünenthal wholly refuted this and wished to convey in the strongest terms that it took its commitment to the Code, in both the letter and the spirit, actively in all that it did, both internally and externally.

Employees could raise queries or concerns through a number of routes although their line manager should be their first point of contact, failing that they could contact their functional compliance champion, the head of compliance or any member of the senior management team – the company was of a size that there was not a great hierarchy therefore senior managers were well known within the business. In addition, there was a general UK compliance email to which they could send queries if they did not know which individual to contact. Employees could also raise concerns anonymously using the Grünenthal Global Ombuds Hotline. This directed concerns to global compliance in Germany, which managed the report. The hotline was made available in 2013 but as yet there had been no reports logged from the UK.

In summary Grünenthal was disappointed to have received this complaint, and queried why the complainant felt unable to raise his/her concerns internally if he/she genuinely felt there were compliance-related issues. The company could not identify any queries which had not been responded to and had no record of any concerns being flagged on the topics outlined above.

Grünenthal strongly refuted the complainant's allegations with regard to inappropriate proactive engagement with health professionals and disguised or off-licence promotion. It had no evidence that high standards had not been maintained, that health professionals were spoken to who would not reasonably be assumed to have an interest in the management of pain or that MSL interactions inconvenienced health professionals. The company believed that all its staff, including the MSLs, conducted themselves in an ethical manner upholding high standards, and therefore did not believe that there had been any action that could discredit or reduce confidence in the industry. The company acknowledged that there was a lack of written briefing documents for the MSLs about the proactive discussions they were to have with oncologists and palliative care specialists as per the email provided by the complainant, and that this was not good business practice. It confirmed that the MSL team was a non-promotional team, and its only proactive activity was to introduce its role to health professionals, as supported by the Medical Science Liaison Policy. The company could see why information in the email provided by the complainant might be seen to be unclear regarding expectations in the absence of a more formalised briefing, however the non-promotional nature of the MSL role was emphasised in many other documents including the job description, the Medical Science Liaison Policy, and the MSL introductory leavepiece.

PANEL RULING

The Panel noted the complainant's allegation that since the 2015 company conference MSLs had been required to proactively target oncologists and palliative care health professionals, introduce themselves and try to steer the conversation to discuss products, particularly Palexia Oral Solution. The Panel further noted the complainant's submission that Grünenthal pain products were not licensed in palliative care and so the MSLs' activity would be disguised promotion of an off-

licence indication. In support of his/her allegations, the complainant had provided copies of two short emails from his/her manager which provided the target list of health professionals, with instructions as to its use, and a reminder to update calendars respectively. The complainant subsequently provided two lists of health professionals which had been entitled by hand 'unlicensed customer group, palliative care and oncology' and 'target list' respectively. The Panel noted that the Constitution and Procedure clearly stated that a complainant had the burden of proving his/her complaint on the balance of probabilities.

The first email provided by the complainant was not dated, it was headed 'MSL Pall_Oncology List'; it was sent by the head of MSLs and described how each MSL should select their business unit to reveal their target list of customers. The MSLs were instructed to look at the top 100 people from their list, check with colleagues if they were already doing business with those individuals and determine whether seeing an individual would have a negative impact. Once satisfactory, the lists could be finalised and would form part of the end of year assessments. The second email headed 'Every day is a field day' was sent on 2 June 2015 and asked those MSLs who had not already done so to update their calendars with where they would be in the field given Grünenthal's new focus. The Panel noted that whilst neither email instructed MSLs to discuss products it appeared that the MSLs would be assessed on the percentage of health professionals seen on their 'proactive' target lists. This appeared to be contrary to the Medical Science Liaison Policy (effective from December 2015) which stated that remuneration for MSLs must not be linked to number of visits, meetings etc. but a bonus scheme linked to the percentage of enquiries or visit **requests** (emphasis added) completed might be acceptable.

The Panel noted Grünenthal's submission that the current (undated) MSL job description was effective from June 2015. The alleged activity referred to by the complainant occurred from the end of April 2015 so the previous (also undated) version of the job description was also relevant. The Panel noted, however, that both versions were identical. The Panel noted that the MSL job descriptions described the role as being field-based. In the Panel's view it was thus not necessarily unacceptable for MSLs to be in the field every day provided that the activities carried out whilst in the field complied with the Code. The Panel noted Grünenthal's submission that the role of the MSLs was non-promotional in action and intent. However the Panel noted that both MSL job descriptions stated at the outset that the position provided support to the medical department in order to achieve the company's goals. The overall purpose of the role included, *inter alia*, to introduce and build new product awareness and facilitate formulary submissions. MSLs were required to identify and develop strong sustainable relationships with external customers to deliver the opportunity to execute product strategy. The Panel noted that the Working Instruction for the MSLs (which was in place over the first six months in question (June-November 2015)) and the Medical Science Liaison Policy which succeeded it, both allowed MSLs to proactively introduce their role. In that regard the MSL introductory leavepiece listed a number of services available including, *inter alia*, 'information on effective and appropriate use of Grünenthal pain products'. The Panel queried whether requests for information received in response to the leavepiece/ introductory visit were, in effect, solicited and so responses to them would not be exempt from the definition of promotion. Overall, the Panel considered that, given the broad definition of promotion in Clause 1.2 of the Code, elements of the MSL role were promotional. In that regard, the MSLs were thus covered by the requirements in the Code for representatives including, *inter alia*, Clauses 15 and 16. Representatives were defined in Clause 1.7 as representatives calling on members of health professionals and other relevant decision makers in relation to the promotion of medicines.

The Panel noted Grünenthal's submission that before the target list was emailed there were verbal discussions with the MSL team in preparation of the release of the list (objectives, actions required, measures that would be used, inclusion in assessment priorities). The Panel was concerned that Grünenthal had not provided any written briefing document to accompany the target list particularly as this was a new way of working for the MSLs. The Panel noted that Grünenthal confirmed that there were never any instructions provided to 'steer conversation' towards any of Grünenthal's products. The Panel also noted that in the first 6 months of setting the MSLs a new way of working (June – December 2015), only two team meetings were held; one in June to discuss target lists and priorities and one in October for which there was no agenda. Meetings in 2016 (January – June) were held in every month but February. No minutes were available from any meeting. The Panel noted Grünenthal's submission that all future meetings would be documented. The Panel considered that the lack of any record of the MSL team discussions was regrettable. It meant that the company had no evidence to support its submission that MSLs were not instructed to steer the conversation towards Palexia Oral Solution or any of Grünenthal's products or that they were not otherwise briefed in a way that would advocate, either directly or indirectly, a course of action which would be likely to lead to a breach of the Code. The Panel noted that the complainant bore the burden of proof to establish that, on the balance of probabilities, MSLs were so briefed. The Panel noted its comment above that the emails provided by the complainant did not instruct MSLs to discuss products. In the circumstances, no breach of Clause 15.9 was ruled.

The Panel noted that Clause 15.4 required representatives to ensure that the frequency, timing and duration of calls on health professionals and other relevant decision makers in hospitals and NHS and other organisations, together with the manner in which they were made, did not cause inconvenience. The wishes of individuals on whom representatives wished to call and the arrangements in force at any particular establishment, must be observed. The Panel noted Grünenthal's submission

that nothing was ever raised directly from any MSL or in association with this complaint to suggest that a health professional had been inconvenienced by an MSL, nor that arrangements at any particular establishment were not observed. On the basis of the evidence before it the Panel ruled no breach of Clause 15.4.

The Panel noted that Clause 3.2 stated that the promotion of a medicine must be in accordance with the terms of its marketing authorization and must not be inconsistent with the particulars listed in its summary of product characteristics. The Panel noted its comments above and Grünenthal's submission that in the sample of call notes reviewed during the investigation into this complaint, there were no recorded discussions of Palexia Oral Solution or any other Grünenthal medicine in a proactive MSL call. The Panel considered that there was no evidence before it to suggest that the MSLs had promoted any medicine, for off-licence use or otherwise, as alleged and therefore ruled no breach of Clause 3.2. There was thus no evidence to suggest that there had been disguised promotion. No breach of Clause 12.1 was ruled.

The Panel noted Grünenthal's submission that introduction of the MSL role to oncologists and palliative care health professionals was defined as a priority given that the number of RFIs received from these specialists demonstrated their need for information. A review of requests for information logged in the medical information system identified 200 queries from health professionals that flagged positive for the words 'oncology' 'palliative' 'cancer' between 17 May 2013 and 18 May 2015. The Panel considered that given these figures oncologists and palliative care health professionals' need for, or interest in information about Grünenthal's products could reasonably be assumed and no breach of Clause 11.1 was ruled.

The Panel did not consider that the complainant had provided evidence to show that on the balance of probabilities the MSLs or Grünenthal had failed to maintain high standards. No breach of Clauses 15.2 and 9.1 were ruled. The Panel noted its rulings above and consequently ruled no breach of Clause 2.

Complaint received **20 June 2016**

Case completed **14 September 2016**