DIRECTOR OF PHARMACY v GRÜNENTHAL

Conduct of a representative

A director of pharmacy complained about the conduct of a representative from Grünenthal. The representative had promoted Palexia (tapentadol) and Versatis (lidocaine). Palexia was indicated for the relief of moderate to severe acute pain in adults, which could be adequately managed only with opioid analgesics. Versatis was indicated in adults for the symptomatic relief of neuropathic pain associated with previous herpes zoster infection.

The complainant alleged a significant amount of promotional material for Palexia and Versatis had been left on one of the care of the elderly wards in his hospital with the intention of promoting to staff, patients and carers. The complainant provided some of the material retrieved by one of the pharmacists from the ward.

The complainant further alleged that the representative had stated that the pharmacy department actively sought to curtail consultants' freedom to prescribe Grünenthal products; this despite the presence of both Palexia and Versatis on the local formulary.

The complainant alleged that in his view the behaviours exhibited breached the Code.

The detailed response from Grünenthal is given below.

The Panel noted that the Grünenthal representative conducted a promotional meeting with ward staff, the meeting being held in a room at the closed end of a short corridor which was remote from, and to one side of, the bed area. Grünenthal stated that the room was for the use of clinical staff only. In the Panel's view, given the ward layout, it was unlikely that carers or patients would have used the corridor or entered the staff room. The Panel noted that the representative took material to the meeting for 12 attendees; only 8 turned up and one took some of the leftover material for a colleague. The representative left the remaining material in the staff room.

The Panel noted that the complainant had alleged that the material had been found 'on the ward' by a colleague; he had not described where on the ward the material had been found. The Panel noted that even if some of the material had been found in an area accessible by patients or carers the complainant had provided no information to prove that, on the balance of probabilities, it had been left there by the representative – it could have inadvertently been put down by one of the attendees. Once leavepieces and the like were given to staff, representatives had no control of what happened to them.

The Panel considered that the complainant had not established, on the balance of probabilities, that the representative had left promotional material on a part of the ward accessible to patients and carers. The material had been distributed to those categories of persons whose need for or interest in it could be reasonably assumed. No breach of the Code was ruled.

With regard to the spare material which was left by the representative, the Panel considered that although it might be good practice to have removed the material at the end of a meeting, whether it was acceptable to do otherwise would depend on a number of factors such as the location and general use of the area in which the material was left and the amount which was left. In the Panel's view, it was not unreasonable, in the context of a pre-planned meeting, to leave promotional material for those who had been expected to attend but were absent on the day. The material had been left in a room used by clinical staff following a promotional meeting with health professionals. In any event, the Panel noted its comments above about a representative having no way of controlling what health professionals did with material after a meeting was finished. On balance, the Panel ruled no breach of the Code.

The Panel noted that the briefing material for the Versatis and the Palexia leavepieces clearly informed representatives that the materials were promotional items for health professionals which should not be left with receptionists or secretaries unless specifically requested to do so, in writing, by a health professional. The Palexia briefing stated that the item 'should only be left with [health professionals] following a promotional call'. The Versatis leavepiece briefing clearly stated that the leavepiece was not to be left with or shown to patients. In the Panel's view none of the briefing material advocated either directly or indirectly that the leavepieces should be used with patients or carers in a way which would be likely to breach the Code. No breach of the Code was ruled.

The Panel noted the complainant's allegation that the representative had stated that the pharmacy department was actively trying to curtail prescribing of Grünenthal's medicines despite the fact that both Palexia and Versatis were on the formulary. The Panel noted Grünenthal's submission regarding what appeared to be confusion about the prescribing of Palexia to in-patients and that it could only be prescribed if a form, ordinarily used for the assessment and approval of high cost medicines, was completed and submitted. In the Panel's view, given Grünenthal's account of the apparent confusion about how Palexia could be prescribed, it was not unreasonable for the representative to try to find out what the situation was. Grünenthal had submitted that some health professionals in the hospital had expressed frustration about the matter. Overall, the Panel did not consider that

it had any information before it to show that in trying to establish the facts, the representative had disparaged the opinions of any health professional. No breach of the Code was ruled.

The Panel noted its rulings above and did not consider that the representative had failed to maintain a high standard of ethical conduct. No breaches of the Code were ruled.

A director of pharmacy complained about the conduct of a representative from Grünenthal Ltd. The representative had promoted Palexia (tapentadol) and Versatis (lidocaine).

Palexia was indicated for the relief of moderate to severe acute pain in adults, which could be adequately managed only with opioid analgesics. Versatis medicated plaster was indicated for the symptomatic relief of neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia, PHN) in adults.

COMPLAINT

The complainant stated that it had been brought to his attention that during September 2015, a significant amount of promotional material for Palexia and Versatis had been left on one of the care of the elderly wards in his hospital with the intention of promoting to staff, patients and carers. The complainant provided some of the material retrieved by one of the pharmacists from the ward. The complainant alleged breaches of Clauses 11.1 and 11.2.

The complainant stated that he was later informed that the Grünenthal representative had stated that in his/her view the pharmacy department in the trust actively sought to curtail consultants' freedom to prescribe Grünenthal products; this despite the presence of both Palexia and Versatis on the local health economy formulary as part of the pain management guidelines. The formulary was overseen by the health economy formulary management group which consisted of GPs, consultants, pharmacists and patients. The complainant alleged that this displayed a poor knowledge of the organisation, in breach of Clauses 8.2, 9.1 and 15.2.

The complainant stated that he had written to Grünenthal with his concerns.

The complainant stated that in his view the behaviours exhibited were in breach of the Code, unwelcome and detrimental to an active professional relationship which was desired with the pharmaceutical industry.

When writing to Grünenthal, the Authority asked it to respond in relation to Clauses 8.2, 9.1, 11.1, 11.2 and 15.2 of the Code as cited by the complainant. In addition Grünenthal was asked to respond in relation to Clause 15.9.

RESPONSE

Grünenthal confirmed that the complainant had contacted the company in advance of his complaint to the PMCPA. Grünenthal submitted that it had asked the complainant for more specific details associated with the allegations but they had not been forthcoming (copies of the correspondence was provided). Grünenthal noted that the details and sequence of events contained within the letter sent to the company differed from that sent to the PMCPA.

With regard to the allegation that significant amounts of promotional materials were left on a care of the elderly ward, with the intention of promoting to staff, patients and carers, Grünenthal noted that all healthcare interactions were logged within the company's customer record management (CRM) system. The data indicated that there was only one meeting in the care of the elderly department in September 2015. Grünenthal confirmed that the representative in question had passed the ABPI Examination for Representatives and a copy of the certificate was provided.

At an investigatory interview to discuss the details of the meeting, the representative in question confirmed that pharmaceutical companies were invited to hold meetings with the care of the elderly team in a private staff room adjacent to the ward. Grünenthal noted that a hand drawn schematic of the room in relation to the patient areas of the ward (copy provided) showed that the room was separated from patient areas of the ward and located at the end of a corridor beside the staff kitchen so no through traffic passed the room. Bins for confidential waste and a stack of chairs hindered easy access along the far end of the corridor to the staff room and the staff kitchen; this would be inappropriate and a health and safety issue if the area was accessed by patients and carers, especially as patients admitted onto a care of the elderly ward might use walking or mobility aids. The small staff room was available for clinical staff only.

The representative confirmed that he/she met eight health professionals and asked each of them to sign an attendance register (copy provided). The representative confirmed that he/she promoted Versatis and Palexia to those who attended. Promotional material for each product was displayed along with food and beverages for the participants.

The representative had expected twelve people to attend the meeting but on the day only eight members of the team were able to attend. In readiness for the meeting, the representative had prepared and displayed twelve copies of three promotional leavepieces. Each attendee took a copy of each item, and one attendee took additional copies to share with a colleague(s) unable to attend. The representative could not recall if this individual took one or more additional copies of each item. At the end of the meeting, the representative left the remaining leavepieces in the room and strongly refuted that this constituted a 'significant' amount of promotional material as there might have been a maximum of three copies of each. The representative was very clear in that no promotional material was left in any area within the vicinity of the ward that patients or carers could access.

Three promotional leavepieces were provided at the meeting, two for Versatis and one for Palexia.

Grünenthal briefly described the content and purpose of each leavepiece and submitted that each was appropriate to provide health professionals from a care of the elderly department.

Copies of each item along with the associated approval certificate and briefing material (Clause 15.9) on how to use each item were provided. Copies of the summary of product characteristics (SPC) for each product and details of the qualifications of the signatories who certified the promotional items and the briefing material were also provided.

Grünenthal submitted that the volume of promotional material provided at the pre-planned meeting was appropriate with reference to the number of health professionals expected to attend it, and the number of people who were able to attend on the day. In addition Grünenthal confirmed that no promotional material was provided to, nor left in areas used by, patients or carers. Grünenthal therefore denied breaches of Clauses 11.1 and 11.2.

Grünenthal stated that with regard to the complainant's allegation that the representative was of the view that the pharmacy department in the trust actively sought to curtail consultants' freedom to prescribe Grünenthal products, Grünenthal stated that in interviewing the representative, it became clear that a genuine level of confusion existed within the hospital with regard to the prescribing of Palexia to in-patients (this was not the case for referrals). The representative stated that during numerous interactions with health professionals at the hospital, he/she had been told that there had been difficulties prescribing Palexia. The complainant was correct that the published joint local formulary and associated guidelines for both primary and secondary care positioned Palexia after co-codamol, tramadol, morphine, buprenorphine, and oxycodone /Fentanyl patch, and the representative confirmed that he/she promoted Palexia in line with these guidelines. In practice, however, he/she had been told that there were difficulties prescribing Palexia to in-patients, even when in line with the agreed published guidelines of use.

A care of the elderly nurse recently told the representative that patients were 'waiting to go on Palexia which is a shame'. Three named care of the elderly consultants stated that they had been 'stopped from prescribing Palexia', and 'we want to prescribe Palexia but we can't'. The representative stated that he/she had been consistent in his/her response, asking why these issues existed, to which each individual had stated they did not know or could not understand it. The representative had noted that Palexia was included within the formulary to which everyone had said they were aware but they still had problems prescribing it for in-patients. The representative had asked that the individuals themselves request further clarification as he/she had no additional information.

As the representative had been told of the issues from the individuals referred to above, he/she sought clarification and asked a named pain consultant from the hospital if this was actually correct. As a result of this dialogue, the pain consultant requested a meeting with the complainant in August 2015 to clarify the situation. The complainant declined and so the consultant met with two other representatives of the pharmacy department instead. At this meeting which took place in either late August or early September, the consultant was informed that the use of Palexia with in-patients was only possible after a form was completed and submitted; the form was ordinarily used for the assessment and approval of high cost medicines and the consultant had not heard of it being used for other purposes. The use of the form for Palexia was not described within the guidelines published by the trust, and its use for Palexia could not be understood when the most commonly prescribed form, Palexia SR 50mg, cost £24.91 for a 56 tablet pack and £12.46 for a 28 tablet pack. This was in comparison to very expensive medicines used in oncology and orphan diseases which had very high associated costs for which the use of the form would be appropriate. The volume of prescribing by the hospital was low so it could not be claimed that this decision had been influenced by the amount of money the hospital spent on Palexia. A strategic consultant to the pain department within the hospital who also attended the meeting reportedly advised the named pain consultant that he needed to push back on the use of the form based on its feasibility, stating that it was not the best use of resources nor was it reasonable to be expected to use it. The pain consultant additionally contacted a member of the hospital's drugs and therapeutics committee to see if he could help understand why such issues existed when prescribing Palexia in the hospital. Grünenthal was unaware of any clarification arising from this discussion.

Grünenthal noted that a named consultant from the care of the elderly team was on the trust's medicines management committee. The representative had asked this individual whether he might be able to find out what the overall issue was with regards the use of Palexia in the hospital. The representative asked whether information could be obtained to understand how Palexia could be prescribed according to the published formulary and guidelines and offered to provide appropriate support of whatever kind might be necessary or helpful to the individual. Grünenthal submitted that this conversation might relate to the verbal conversation referred to by the complainant. Given the situation, Grünenthal considered that it was a reasonable question to ask, and it was raised with an appropriate individual; clarification was being sought from many individuals and questions were often directed to the representative by hospital clinicians. The representative refuted the allegation that in asking this question he/she disparaged the clinical or scientific opinions of health professionals. On the contrary, Grünenthal submitted that offering help to health professionals who had approached the representative with these questions supported the clarification and adherence to the formulary position for the product.

Grünenthal understood that in addition to the complications described above, that there were ongoing issues between the pharmacy department

and individuals in the pain department including allegations against individuals, subsequent counter allegations, and internal procedures that had involved the hospital human resources department. Grünenthal submitted that through no fault of its own, it appeared to have been caught up in those disputes and was why this complaint had been submitted.

Grünenthal denied the complainant's allegations with regard to Clauses 9.1 and 15.2. All the representative's materials were certified for use with health professionals, and briefing documents were provided to support their appropriate and compliant use by promotional teams. All material used by the representative was appropriate for care of the elderly staff and he/she provided an appropriate amount of material for the September meeting. The representative was experienced and was clear that he/she had never left promotional material in an area accessible to patients or carers.

The representative refuted the allegation that he/she had disparaged the clinical or scientific opinions of health professionals and maintained that he/she had always maintained a high standard of ethical conduct when working at this and any other hospital.

Grünenthal reiterated its complete commitment to adhering to the Code in all its business activities.

PANEL RULING

The Panel noted that, as stated in the introduction to the Constitution and Procedure, complainants had the burden of proving their complaints on the balance of probabilities. The Panel further noted Grünenthal's submission that it had unsuccessfully requested further details from the complainant. Copies of the correspondence provided showed that the company had sought clarification with regard to, *inter alia*, the location and quantity of promotional material found on the ward and what the representative specifically stated about the use of Grünenthal's medicines in the hospital. Further, in response to the PMCPA's acknowledgement of his complaint, the complainant had stated to the case preparation manager that he had more information should it be required. The case preparation manager asked for the information to be sent as soon as possible but received no reply.

The Panel noted the complainant's allegation that a representative had left a significant amount of promotional material for Palexia and Versatis on a hospital ward, clearly with the intention of promoting to staff, patients and carers. The Panel noted that Grünenthal acknowledged that its representative had conducted a promotional meeting with ward staff, the meeting being held in a room at the closed end of a short corridor which was remote from, and to one side of, the bed area. Grünenthal stated that the room was for the use of clinical staff only. In the Panel's view, given the sketch provided of the ward layout, it was unlikely that carers or patients would have cause to use the corridor or enter the staff room. The Panel noted that the representative took enough material to the meeting for 12 attendees; only 8 turned up on the day one of whom took some of the leftover material to share with an absent colleague. The representative left the remaining material in the staff room. The Panel noted that the representative planned to give three pieces of material to each attendee. Given the number of attendees on the day and the fact that one took at least one piece of material to share with a colleague, the number of pieces left by the representative was unlikely to be more than 11.

The Panel noted that the complainant had alleged that the material had been found 'on the ward' by a colleague. The complainant had not described where on the ward the material had been found. The Panel noted that even if some of the material had been found in an area accessible by patients or carers rather than the meeting room, the complainant had provided no information to prove that, on the balance of probabilities, it had been left there by the representative – it could have inadvertently been put down by one of the attendees. Once leavepieces and the like were given to staff, representatives had no control of what happened to them.

The Panel considered that the complainant had not established, on the balance of probabilities, that the representative had left promotional material on that part of the ward accessible to patients and carers. The material had been distributed to those categories of persons whose need for or interest in it could be reasonably assumed. No breach of Clause 11.1 was ruled.

The Panel noted that Clause 11.2 stated that restraint should be exercised over the frequency of distribution and the volume of promotional material distributed. With regard to the spare material which was left by the representative, the Panel considered that although it might be good practice to have removed the material at the end of a meeting, whether it was acceptable to do otherwise would depend on a number of factors such as the location and general use of the area in which the material was left and the amount which was left. In the Panel's view, in this case it was not unreasonable, in the context of a pre-planned meeting, to leave copies for those who had been expected to attend but were absent on the day. The material had been left in a room used by clinical staff following a promotional meeting with health professionals. In any event, the Panel noted its comments above about a representative having no way of controlling what health professionals did with material after a meeting was finished. On balance, the Panel ruled no breach of Clause 11.2.

The Panel noted that the briefing material for the Versatis leavepiece (ref UK/V15 0012) and the Palexia leavepiece (ref UK/P14 0021b) clearly informed representatives that the materials were promotional items for health professionals which should not be left with receptionists or secretaries unless specifically requested to do so, in writing, by a health professional. The Palexia briefing stated that the item 'should only be left with [health professionals] following a promotional call'. The briefing material for the Versatis leavepiece (ref V12 0051(1)) clearly stated that the item was not to be left with or shown

to patients. In the Panel's view none of the briefing material advocated either directly or indirectly that any of the leavepieces should be used with patients or carers in a way which would be likely to breach the Code. No breach of Clause 15.9 was ruled.

The Panel noted the complainant's allegation that the representative had stated that the pharmacy department was actively trying to curtail prescribing of Grünenthal's medicines despite the fact that both Palexia and Versatis were on the formulary. The Panel noted Grünenthal's submission regarding what appeared to be confusion about the prescribing of Palexia to in-patients and that it could only be prescribed if a form, ordinarily used for the assessment and approval of high cost medicines, was completed and submitted. In the Panel's view, given Grünenthal's account of the apparent confusion about how Palexia could be prescribed, it was not unreasonable for the representative to try to find out what the situation was. Grünenthal had submitted that some health professionals in the hospital had expressed frustration about the matter. Overall, the Panel did not consider that it had any information before it to show that in trying to establish the facts, the representative had disparaged the opinions of any health professional. No breach of Clause 8.2 was ruled.

The Panel noted its rulings above and did not consider that the representative had failed to maintain a high standard of ethical conduct. No breach of Clauses 15.2 and 9.1 were ruled.

Complaint received **6 October 2015**

Case completed **16 November 2015**