CASE AUTH/2513/6/12 NO BREACH OF THE CODE

ANONYMOUS EMPLOYEE v GRÜNENTHAL

Promotional mailings

An employee of Grünenthal complained anonymously about the frequency and volume of Palexia (tapentadol) promotional mailings sent to health professionals and alleged that target customers would be sent a mailing after every call. The complainant noted that the Code stated that 'Restraint must be exercised on the frequency of distribution and on the volume of promotional material distributed' and that 'No more than eight mailings for a particular medicine may be sent to a health professional in a year. The complainant alleged that as Palexia mailings were sent to target customers after every call, in addition to other Palexia mailings, some customers could get more than eight mailings in a year and/or several mailings in a short space of time.

The detailed response from Grünenthal is given below.

The Panel noted that the supplementary information referred to by the complainant stated, et al, that in the first six months following the launch of a new medicine, a health professional could be sent up to four mailings about the medicine and that no more than eight mailings for a particular medicine might be sent to a health professional in a year.

The Panel noted that a marketing newsletter provided by the complainant implied that a Palexia brand reminder mailing would be sent to target GPs after every call. Grünenthal submitted that this was not so; the mailing would only be sent once, following the first contact with the customer in relation to Palexia from April 2012. This point could have been more clearly stated in the newsletter.

With regard to the volume of mailings the Panel noted that Grünenthal had provided information to show that between February 2011 and June 2012 no GP would have received more than four Palexia mailings and the maximum number received by any hospital health professional was two. The Panel considered that there was no evidence to show that any health professional had received more than eight mailings in a year as alleged. No breach of the Code was ruled.

With regard to the frequency of mailings the Panel noted that it was possible that some GPs might have received the MIMS Palexia announcement mailing (sent March 2012), the brand reminder mailing (sent from April 2012) and two mailings about a meeting (sent May-June 2012) in successive months. The Panel considered that in the circumstances this was not unacceptable. No breach of the Code was ruled.

The Panel consequently considered that with regard to the requirements for mailings there had not been

a failure to maintain high standards. No breach of the Code was ruled.

An anonymous, non-contactable employee of Grünenthal Ltd complained about the frequency and volume of Palexia (tapentadol) promotional mailings sent to health professionals.

COMPLAINT

The complainant alleged that after every call made on a target customer, Grünenthal sent that customer a Palexia 'brand reminder mailer' and dosage card. The complainant noted that Clause 11.2 of the Code stated that 'Restraint must be exercised on the frequency of distribution and on the volume of promotional material distributed' and also that 'No more than eight mailings for a particular medicine may be sent to a health professional in a year'. As mailings were sent after every call made on target customers, in addition to other promotional mailings for Palexia, some customers could get more than eight mailings in a year and/or several mailings in a short space of time.

The complainant provided a copy of a marketing newsletter which was sent to representatives in March. The newsletter stated that the brand reminder mailing would enhance the memorability of representatives' calls. The reader was informed that 'Your call on any IPTI customer with Palexia will be picked up in [the customer relationship management system], and then within 7 days we will mail the customer a letter and an additional dosage card reminding them of the call you made. This will start from the end of March.' The newsletter also referred to a second mailing programme which would also start in March, ie the MIMS product announcement on Palexia which would go to 10,000 UK specialists.

When writing to Grünenthal, the Authority asked it to respond in relation to Clauses 9.1 and 11.2 of the Code.

RESPONSE

Grünenthal explained that the Palexia brand reminder mailing (ref P12 0056a), referred to by the complainant was designed as a contact-activated mailer to selected GPs (maximum 4,500). The mailing consisted of a letter which reviewed the content of that contact and a dosage and titration leavepiece (ref P12 0056). The mailings were first sent out in April 2012 and this initiative would continue until December 2012. The process behind the mailing was automatic to ensure that it was only sent once to any GP during its eight month active period.

Grünenthal explained that the representative entered their activity into the company's customer relationship management system on a weekly basis. At the end of each week the software generated a list of those health professionals who had been seen for the first time since April 2012 with Palexia.

This list was sent to a mailing provider and it checked the list against previous 2012 recipients of the mailing to ensure no duplication could occur. Once the list was finalised, the mailing was posted with the dosage card to the health professional. To date, since April 2012, the mailing had been sent to nearly 500 GPs. The overall list of those who had received the mailing since April 2012 was stored at the mailing provider and was available to Grünenthal's marketing team.

Grünenthal submitted that for planning purposes the brand reminder mailing counted as one promotional mailing contact per health professional for Palexia, to the company's selected group of GPs.

Grünenthal further explained that the MIMS product announcement mailing (ref P12 0029) was a one-off mailing sent in March 2012 to 11,000 GPs. The list was mailed by MIMS and Grünenthal's marketing team had access to the full list of recipients. Again, for planning purposes this mailing counted as one promotional mailing contact per health professional for Palexia to a selected group of GPs.

Grünenthal submitted that, overall, its brand planning process determined and clarified the intended activity regarding promotional posted mailings over the calendar year for each product in line with the requirements of the Code. This process for any year was usually completed and agreed during October of the previous year, and the review process ensured that the volume and frequency of planned mailings was regulated and appropriate. It also ensured that a health professional did not receive several mailings in a short period of time. There were planned promotional mailings for Palexia throughout 2012. The list of intended audiences for those mailings was maintained in a smartsheet excel planner, which gave a clear overview of the maximum number of promotional mailings that any health professional could receive from Grünenthal about Palexia.

Grünenthal provided information of promotional mailings for Palexia that had been sent to health professionals since February 2011. In addition to the brand reminder mailing (from April - December 2012) and the MIMS product announcement mailing (March 2012), GPs in two English counties received a mailing about a meeting (May/June 2012) (which had to be re-sent to one group due to a date change (June 2012)). With regard to secondary care, Grünenthal had invited some key opinion leaders to a round table meeting (September 2011) and 200 health professionals to a meeting in London (May 2012). Five hundred secondary care health professionals in Scotland had been sent a Palexia SMC (Scottish Medicines Consortium) mailing (May 2012). Grünenthal submitted that from February 2011 to June 2012, and allowing for the on-going nature of the contact-activated mailings, and the geographies

used for other mailings, the maximum number of Palexia promotional mailers that any single GP could have received in that time was four and any single secondary care health professional was two.

Grünenthal concluded that it had demonstrated that it operated within the Code regarding the frequency and volume of promotional mailings and it thus denied a breach of Clause 11.2. Grünenthal considered that it had maintained high standards at all times and it thus denied a breach of Clause 9.1.

PANEL RULING

The Panel noted that Clause 11.2 of the Code stated that restraint must be exercised on the frequency of distribution and on the volume of promotional material distributed. Supplementary information to the clause stated, *et al*, that in the first six months following the launch of a new medicine, a health professional could be sent up to four mailings about the medicine and went on to state that no more than eight mailings for a particular medicine might be sent to a health professional in a year.

The Panel noted that the marketing newsletter provided by the complainant implied that a Palexia brand reminder mailing would be sent to target GPs after every call. Grünenthal submitted that this was not so; the mailing would only be sent once, following the first contact with the customer in relation to Palexia from April 2012. This point could have been more clearly stated in the newsletter.

With regard to the volume of mailings the Panel noted that Grünenthal had provided information to show that between February 2011 and June 2012 no GP would have received more than four Palexia mailings and the maximum number received by any hospital health professional was two. The Panel considered that there was no evidence to show that any health professional had received more than eight mailings in a year as alleged. No breach of Clause 11.2 was ruled.

With regard to the frequency of mailings the Panel noted that it was possible that some GPs in one English county who had met a Grünenthal representative and discussed Palexia might have received the MIMS Palexia announcement mailing (sent March 2012), the brand reminder mailing (sent from April 2012) and two mailings about a meeting (sent May-June 2012 – the second mailing was sent due to a date change) in successive months. The Panel considered that in the circumstances this was not unacceptale. No breach of Clause 11.2 was ruled.

The Panel consequently considered that with regard to the requirements for mailings there had not been a failure to maintain high standards. No breach of Clause 9.1 was ruled.

Complaint received 13 June 2012

Case completed 26 June 2012