

MEDICINES INFORMATION PHARMACIST v GRÜNENTHAL

Versatis brochure

A medicines information pharmacist complained about a brochure entitled 'Overview and Budget Impact Bulletin: Versatis (5% lidocaine medicated plaster) for localised pain of post-herpetic neuralgia [PHN]' issued by Grünenthal.

The complainant noted that a table, 'Results of the Base Care Analysis (Per Patient)' compared various features of Versatis and gabapentin including the total NHS cost of each. The cost for Versatis was stated as £845, for gabapentin it was £718 with £128 stated as the difference. The complainant alleged that it was misleading to state that gabapentin cost £718 for six months' treatment. There were two forms of gabapentin. If capsules were used for a high dose (800mg three times a day) it would cost only £280 for six months using the price from the Drug Tariff February 2007. The complainant suspected that the price of tablets was used and this was misleadingly expensive.

The Panel noted that the complainant had interpreted 'Total NHS cost' as referring only to the acquisition cost of the medicine whereas Grünenthal submitted that the 'Total NHS cost' for gabapentin referred to the total cost of treatment for six months and included, *inter alia*, the costs of consultations and additional medication. The Panel did not consider that the table at issue was sufficiently clear as to what was meant by the term 'Total NHS cost'. The Panel considered that the impression that 'Total NHS cost' only related to acquisition costs was strengthened by a statement in the text above the table of data which did relate to the acquisition costs of Versatis. The Panel ruled that the data in the table was misleading and thus in breach of the Code.

A medicines information pharmacist complained about a 12 page brochure (ref 064/GRTUK/VERS 12/06-12/08) entitled 'Overview and Budget Impact Bulletin: Versatis (5% lidocaine medicated plaster) for localised pain of post-herpetic neuralgia [PHN]' issued by Grünenthal Ltd. The prescribing information for Versatis, on the back page of the brochure, stated that patients could use up to three plasters for up to 12 hours, followed by at least a 12 hour plaster-free interval.

The brochure was mailed to primary care trust (PCT) and hospital budget holders following the grant of Versatis' marketing authorization. It also formed part of a formulary pack used by representatives.

COMPLAINT

The complainant noted that a table of data, 'Results of

the Base Care Analysis (Per Patient)' compared various features of Versatis and gabapentin including the total NHS cost of each. The cost for Versatis was stated as £845, for gabapentin it was £718 with £128 stated as the difference.

The complainant alleged that it was misleading to state that gabapentin cost £718 for six months' treatment. There were two forms of gabapentin. If capsules were used to make a high dose, of say 800mg three times a day, it would cost only £280 for six months using the price from the Drug Tariff February 2007. The complainant suspected that the price of tablets was used and this was misleadingly expensive.

When writing to Grünenthal the Authority asked it to respond in relation to Clause 7.2 of the Code.

RESPONSE

Grünenthal submitted that the complainant had misunderstood the table of data. The complainant referred to the price of gabapentin whereas the table referred to the total NHS cost of gabapentin treatment.

The £718 total NHS cost of gabapentin treatment included not only the medicine acquisition costs but also the total costs for the whole treatment over six months.

Resource utilisation data were included in the health economic model (Markov model), and covered the following:

- 1 Costs for gabapentin. The calculation had to differentiate between the first month (titration period according to Prodigy guidelines) and the following five months' maintenance treatment.
- 2 Costs for additional medicine. For some patients (>40%) gabapentin monotherapy did not provide sufficient pain relief in PHN and so they received additional medication (the same was true and calculated for Versatis). Additional medication was calculated based on information from a Delphi panel and according to Prodigy guidelines.
- 3 Consultations. From English physicians (Delphi panel) the company received estimates on the number of consultations (physicians, nurses or telephone), necessary for titration of gabapentin and within the maintenance phase.
- 4 Switch medication. For all patients who discontinued gabapentin treatment the medication was documented, which was applied for the remaining months, until the end of the six month period. Switch medication corresponded to Prodigy

guidelines and included a mixture of the treatment armentarium used in PHN.

- 5 Referrals. The Delphi panel estimated the number of patients who were referred to specialists after dropping-out, discontinuing gabapentin treatment. Accordingly, costs were defined for the referrals.

Respective costs were calculated for six months' treatment with Versatis which resulted in £845 treatment costs.

In conclusion Grünenthal submitted that it had not produced incorrect or misleading information relating to a competitor product.

PANEL RULING

The Panel noted that the data in question appeared on a page headed 'Versatis: clinical effectiveness and budget impact'. Some of the detail relating to the data was explained above the table in question. The cost of Versatis treatment was based on an average of 1.89 plasters used per day which was the weighted mean from clinical trials. It was stated that it had been assumed that treatment would be for a six month period.

The Panel noted that the complainant had interpreted 'Total NHS cost' as referring only to the acquisition cost of the medicine whereas Grünenthal submitted that the 'Total NHS cost' for gabapentin referred to the total cost of treatment for six months and included the cost of the medicine as well as the cost of consultations with health professionals, switch medication for those that discontinued gabapentin, and additional medication when gabapentin alone did not provide sufficient pain relief.

The Panel did not consider that the table at issue was sufficiently clear as to what was meant by the term 'Total NHS cost'; the text above the table did not give sufficient details in this regard. The Panel considered that the impression that 'Total NHS cost' only related to acquisition costs was strengthened by a statement in the text above the table of data which did relate to the acquisition costs of Versatis. The Panel considered that the data in the table was misleading and thus a breach of Clause 7.2 was ruled.

During its consideration of this case the Panel noted that the calculation for Versatis was based on 1.89 plasters per day at an average cost of £4.55 per day. The Panel noted that plasters could be cut to cover the particular site but queried whether it was appropriate to base the calculation on 1.89 plasters when in effect the patient would need two plasters each day even if only 1.89 daily were used. Page 2 of the brochure stated that the anticipated cost of Versatis was £4.57 per day based on an average use of 1.89 plasters per day. The Panel queried whether the total NHS cost for Versatis was actually as stated ie £845. If one patient used 1.89 plasters at a cost of £4.55 (£4.57) per day for six months the cost of medication would be £828.10 (£831.74) leaving £16.90 (£13.26) over for the cost of consultations or additional medication if necessary. The Panel did not have all the data for Versatis but on the information presented in the booklet queried whether the figures for the total NHS costs of Versatis and gabapentin were calculated on a similar basis. The Panel requested that its concerns be drawn to Grünenthal's attention.

Complaint received **6 February 2007**

Case completed **20 March 2007**