CASE AUTH/2330/7/10

ANONYMOUS v GRÜNENTHAL

Promotion of unlicensed indication in poster presentation

An anonymous and uncontactable complainant submitted an item headed 'Localised Neuropathic Pain' which referred to Versatis (lidocaine plaster) a product supplied by Grünenthal. At the foot of the one page document, in very small type, were the words 'Sponsored by an unrestricted grant by Grünenthal UK Ltd'.

Versatis was indicated for the symptomatic relief of neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia, PHN).

The complainant had highlighted: 'Conclusion, Versatis has an "off-label" use for the symptomatic relief of localised neuropathic pain, and could provide a substantial saving to the local health-economy'. The Director interpreted this as an allegation that the document promoted Versatis for an unlicensed indication.

In its detailed response, given below, Grünenthal explained that the item provided by the complainant had the same copy as a poster submitted to the poster session of a meeting of the British Pain Society (BPS) and the accompanying handout.

The Panel noted that Grünenthal had paid for the printing of the poster and had helped with its submission to the BPS; the company stated that it had not had editorial control of the poster. A consultant pharmacist appeared to have led on the development of the poster. The Panel did not know if the consultant pharmacist had been paid by Grünenthal in relation to the poster or had been otherwise retained by the company. A Grünenthal employee had provided information for the poster and was named as the second author although her position with Grünenthal was not declared. The Panel considered it was unacceptable of Grünenthal not to make it clear in its response that one of its employees was named as an author. The Panel considered that given that one of the named authors was a Grünenthal employee, the company could not dissociate itself from the content of the poster. It was difficult to see how in these circumstances Grünenthal could submit it had no editorial control.

The Panel noted that the material provided by the complainant was not the same size as either the poster or the handout; in that regard the material submitted could be a reproduction of either. The complainant had highlighted the phrase 'Versatis has an "off-label" use for the symptomatic relief of localised neuropathic pain, and could provide a substantial saving to the local health-economy'. In the Panel's view this was clearly a complaint about that sentence which appeared on the poster and the handout. The Panel considered the two items separately.

The Panel then considered whether the poster formed part of the legitimate exchange of medical and scientific information during the development of a medicine as submitted by Grünenthal. The certificate showed that the company had purported to approve it as promotional material. The Panel noted that the poster reported the outcome of a retrospective analysis of published literature (after 2000) on the treatment options for localised neuropathic pain. Electronic prescribing data from a primary care trust with a patient population of 500,000 was used as a basis of assumptions for the algorithm. The poster stated that recent literature showed that '…only 1% of PHN patients are prescribed Versatis patches first-line for PHN pain' and approximately 5% of patients trialled on gabapentin and pregabalin tried Versatis as second line. From this the authors predicted that 143 patients from a population of 500,000 would benefit from Versatis in PHN.

The results section referred to prescribing Versatis for the symptomatic relief of localised neuropathic pain and quantified the yearly savings that could be made by using Versatis compared with the cost of gabapentin at 3.6g/day or pregabalin.

The discussion section referred to the challenges of treating neuropathic pain in part due to its multiple aetiologies, symptoms and underlying mechanisms. The review highlighted the various pharmacological options for symptomatic treatment of localised neuropathic pain. It was stated that Versatis was an equitable option for pain management competing with gabapentin and pregabalin as a cost-effective choice and provided a saving to the local health-economy.

The Panel did not consider that the subject of the poster, the cost implications of prescribing Versatis in an unlicensed indication, contributed to the legitimate exchange of medical and scientific information during the development of a medicine as meant by supplementary information to the Code. The Panel queried whether the information presented contributed to the development of the medicine as it could be argued that the information was neither scientific nor medical. In the Panel's view discussion of unlicensed indications was more likely to be seen as promotional when products were already available on the market albeit for different indications. Overall the Panel did not consider that the poster could claim the benefit of the exemption. In the Panel's view the poster

advocated using Versatis for localised neuropathic pain instead of gabapentin or pregabalin solely on the basis of cost. The poster also included a section 'Potential Costing Savings (for PHN)'. The Panel noted that treatment of PHN, a specific type of neuropathic pain, was within the Versatis marketing authorization.

The Panel noted that the abstract for the poster differed from the poster in a number of ways. For example, the abstract clearly stated that a named person was a health economy liaison manager, Grünenthal. Unlike the poster the abstract did not mention the 'off-label' use of Versatis. It was stated in the abstract that the pharmacist and his colleague (the second author named in the abstract and named as third author on the poster/handout) 'received and [sic] educational grant from Grünenthal Ltd for the development of the algorithm'. The poster included a copy of the algorithm, supporting statements, costing estimates and potential cost savings for PHN which were not included in the abstract. The abstract had four references 1-4. The poster cited these four references, listed 1-4, plus another set of references separately numbered 1-29.

The Panel considered that given Grünenthal's role in the production of the poster and its content it was promotional material and thus covered by the Code. The claim at issue promoted Versatis for an unlicensed indication and thus the Panel ruled a breach of the Code. The Panel considered that high standards had not been maintained and ruled a breach of the Code.

The Panel noted that Clause 2 was a sign of particular censure and reserved for such use. The Panel noted its comments above. The Panel was especially concerned that the company had certified the promotional item which referred to an unlicensed indication knowing that it would appear as part of a peer-reviewed poster presentation at a scientific conference. The Panel considered that delegates would be likely to view the material and the statement at issue differently if they knew it was promotional material. The Panel considered that overall the company's activities reduced confidence in the pharmaceutical industry and thus ruled a breach of Clause 2.

The Panel noted Grünenthal's submission that the handout had not been used. In the circumstances the Panel ruled no breach in that regard.

An anonymous and uncontactable complainant submitted an item headed 'Localised Neuropathic Pain' which referred to Versatis (lidocaine plaster) a product supplied by Grünenthal Ltd. At the foot of the one page document, in very small type, were the words 'Sponsored by an unrestricted grant by Grünenthal UK Ltd'.

Versatis was indicated for the symptomatic relief of neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia, PHN).

COMPLAINT

The complainant had highlighted: 'Conclusion, Versatis has an "off-label" use for the symptomatic relief of localised neuropathic pain, and could provide a substantial saving to the local health-economy'.

The Director interpreted this as an allegation that the document promoted Versatis for an unlicensed indication. Grünenthal was asked to respond in relation to Clauses 2, 3.2 and 9.1 of the Code.

RESPONSE

Grünenthal submitted that the item was never approved for promotional use. It was certified as a poster handout.

A consultant pharmacist and his colleague had an informal discussion with the Grünenthal market access director about his local health economic data and getting it published as part of the legitimate exchange of medical and scientific information during the development of a medicine. Grünenthal agreed to support this financially and without editorial control.

The pharmacist subsequently collated his data and asked a health economy liaison manager at Grünenthal a couple of questions about Versatis. Grünenthal helped with the printing of the poster and submission to the British Pain Society (BPS). The poster was peer reviewed by the Scientific Programme Committee and accepted.

Limited data was provided by Grünenthal which did not have editorial control.

A declaration appeared on the bottom of the full sized poster (which was several times bigger than the item at issue) that the item was 'Sponsored by an unrestricted educational grant by Grünenthal Ltd'. A similar declaration appeared at the bottom of the item in question, being an identical but smaller representation of the poster.

The poster was displayed in the poster session of the BPS independent congress meeting (13-15 April in Manchester). It was intended that the item at issue (the handout) would be available under the poster for delegates to take a copy. However, due to the poor print quality, the handout was removed before the congress opened and never used.

The item had never been sent out by medical information and nor had it been used proactively or reactively by any Grünenthal staff.

With respect to Clause 2, the item was developed to support a poster at an independent national congress. It was never used and so there could be no discredit upon the pharmaceutical industry.

In relation to Clause 3.2, the item was produced as part of the legitimate exchange of medical and

scientific information during the development of a medicine and complied with this clause. The item was never intended or used for promotion and had never been used.

Finally concerning Clause 9.1, high standards had been maintained by the intention of limiting the use of this item to the congress's medical and scientific poster session. In the end, it was never used, and certainly not for promotion.

In response to a request for further information Grünenthal stated that the handout was A3 in size. It was common practice to provide a reprint of a poster presentation at a scientific conference. Organisers often requested reprints from poster presenters. In line with this process, Grünenthal thus printed a number of handouts which, apart from size, were identical to the poster.

PANEL RULING

The Panel noted that Grünenthal had paid for the printing of the poster and had helped with its submission to the BPS; the company stated that it had not had editorial control of the poster. A consultant pharmacist appeared to have led on the development of the poster. The Panel did not know if the consultant pharmacist had been paid by Grünenthal in relation to the poster or had been otherwise retained by the company. A Grünenthal employee had provided information for the poster and was named as the second author although her position with Grünenthal was not declared. The Panel considered it was unacceptable of Grünenthal not to make it clear in its response that one of its employees was named as an author. The Panel considered that given that one of the named authors was a Grünenthal employee, the company could not dissociate itself from the content of the poster. It was difficult to see how in these circumstances Grünenthal could submit it had no editorial control.

The Panel noted that the material provided by the complainant was not the same size as either the poster or the handout; in that regard the material submitted could be a reproduction of either. The complainant had highlighted the phrase 'Versatis has an "off-label" use for the symptomatic relief of localised neuropathic pain, and could provide a substantial saving to the local health-economy'. In the Panel's view this was clearly a complaint about that sentence which appeared on the poster and the handout; it decided to consider the two items separately.

The Panel then considered whether the poster formed part of the legitimate exchange of medical and scientific information during the development of a medicine as submitted by Grünenthal. The certificate showed that the company had purported to approve it as promotional material. The Panel noted that the poster reported the outcome of a retrospective analysis of published literature (after 2000) on the treatment options for localised neuropathic pain. Electronic prescribing data from a primary care trust with a patient population of 500,000 was used as a basis of assumptions for the algorithm. The poster stated that recent literature showed that '…only 1% of PHN patients are prescribed Versatis patches first-line for PHN pain' and approximately 5% of patients trialled on gabapentin and pregabalin tried Versatis as second line. From this the authors predicted that 143 patients from a population of 500,000 would benefit from Versatis in PHN.

The results section referred to prescribing Versatis for the symptomatic relief of localised neuropathic pain and quantified the yearly savings that could be made by using Versatis compared with the cost of gabapentin at 3.6g/day or pregabalin.

The discussion section referred to the challenges of treating neuropathic pain in part due to its multiple aetiologies, symptoms and underlying mechanisms. The review highlighted the various pharmacological options for symptomatic treatment of localised neuropathic pain. It was stated that Versatis was an equitable option for pain management competing with gabapentin and pregabalin as a cost-effective choice and provided a saving to the local health-economy.

The Panel did not consider that the subject of the poster, the cost implications of prescribing Versatis in an unlicensed indication, contributed to the legitimate exchange of medical and scientific information during the development of a medicine as meant by the supplementary information to Clause 3, Marketing Authorization. The Panel queried whether the information presented contributed to the development of the medicine as it could be argued that the information was neither scientific nor medical. In the Panel's view discussion of unlicensed indications was more likely to be seen as promotional when products were already available on the market albeit for different indications. Taking all the circumstances into account the Panel did not consider that the poster could claim the benefit of the exemption in the supplementary information to Clause 3, Marketing Authorization. In the Panel's view the poster advocated using Versatis for localised neuropathic pain instead of gabapentin or pregabalin solely on the basis of cost. The poster also included a section 'Potential Costing Savings (for PHN)'. The Panel noted that treatment of PHN, a specific type of neuropathic pain, was within the Versatis marketing authorization.

The Panel examined the abstract for the poster. This was different to the poster in a number of ways. For example, the abstract clearly stated that a named person was a health economy liaison manager, Grünenthal. Unlike the poster the abstract did not mention the 'off-label' use of Versatis. It was stated in the abstract that the pharmacist and his colleague (the second author named in the abstract and named as third author on the poster/handout) 'received and [sic] educational grant from

Grünenthal Ltd for the development of the algorithm'. The poster included a copy of the algorithm, supporting statements, costing estimates and potential cost savings for PHN which were not included in the abstract. The abstract had four references 1-4. The poster cited these four references, listed 1-4, plus another set of references separately numbered 1-29.

The Panel considered that given Grünenthal's role in the production of the poster and its content it was promotional material and thus covered by the Code. The claim at issue promoted Versatis for an unlicensed indication and thus the Panel ruled a breach of Clause 3.2. The Panel considered that high standards had not been maintained and ruled a breach of Clause 9.1.

The Panel noted that Clause 2 was a sign of particular censure and reserved for such use. The Panel noted its comments above. The Panel was especially concerned that the company had certified the promotional item which referred to an unlicensed indication knowing that it would appear as part of a peer-reviewed poster presentation at a scientific conference. The Panel considered that delegates would be likely to view the material and the statement at issue differently if they knew it was promotional material. It considered that taking all the circumstances into account in this instance the company's activities reduced confidence in the pharmaceutical industry and thus ruled a breach of Clause 2.

The Panel noted Grünenthal's submission that the handout had not been used. In the circumstances the Panel ruled no breach of Clauses 2, 3.2 and 9.1.

Complaint received **5 July 2010**

Case completed **19 August 2010**