

DOCTOR v SANOFI PASTEUR MSD

Shingles awareness campaign

A doctor alleged that an advertisement placed by Sanofi Pasteur MSD in a lifestyle magazine was in breach of the Code.

The advertisement, which was presented in the style of an advertorial, had a 'Shingles Aware' logo in the top left-hand corner. The headline read 'If, like 90% of UK adults, you have ever had chickenpox, there is a 1 in 4 chance you will develop shingles at some point in your lifetime'. The following three paragraphs described the symptoms of shingles and advised the reader about the need to see a GP as soon as possible. Following these paragraphs were the separate statements, in a bolder font, 'It is possible to prevent shingles' and 'See your GP who can give you more information'. Readers were then directed to other information on the shingles aware website (sponsored by Sanofi Pasteur MSD) or an independent patient organization website. Readers could scan a QR Code with a smart phone to access the shingles aware website.

Sanofi Pasteur MSD had recently launched Zostavax (shingles (herpes zoster) vaccine (live)) for the immunization of the over 50s to prevent herpes zoster (shingles) and herpes zoster-related post-herpetic neuralgia.

The detailed response from Sanofi Pasteur MSD is given below.

The Panel noted that Zostavax was the only medicine for the prevention of shingles.

The Panel noted that the headline stated that 90% of UK adults had a 1 in 4 chance of developing shingles. The following three paragraphs informed the reader that shingles occurred more frequently in those aged 50 years or more and then described the symptoms of shingles. Although the reader was told that symptoms were 'usually mild', they could be 'very unpleasant for some'. Further details were provided.

The Panel noted that following the paragraphs which described the symptoms of shingles, the statement 'It is possible to prevent shingles' appeared in bolder, darker and thus more prominent font. This statement was clearly separated from the previous text and in that regard the Panel considered that the reader's eye would be drawn to it. This statement was followed by a separate equally prominent statement 'See your GP who can give you more information'. The prominence, font colour and position of the statement was such that some readers would associate it particularly with the preceding statement and conclude that their GP could provide more information particularly on the prevention of shingles. The Panel's view was that the final 'take home' message from the advertisement was one of prevention.

The Panel noted that whilst disease awareness was in principle a legitimate and helpful activity, caution should be exercised when there was only one product available. Whilst the advertisement discussed symptoms and some relatively rare but serious consequences of shingles, there was very little discussion of treatment. The emphasis was on prevention. The Panel queried whether it was sufficiently balanced in this regard given the need to exercise caution.

The Panel considered that companies that published website addresses as an integral part of 'the message' of their material as in the present case, and directed the public to seek further information about that message from such sites needed to be satisfied that the website content was reasonable as far as the Code was concerned. This was so whether or not they had any input to, or ability to, influence the content. If this were not the case then companies could refer to independent sites as a means of circumventing the Code.

Readers were directed to two websites; the company-sponsored shingles aware website and an independent patient organization website. On the homepage of the shingles aware website was a Sanofi Pasteur MSD website and on the home page there were two separate buttons; one marked 'Information for the public' and the other marked 'Information for healthcare professionals'. Below the 'Information for the public' button was the statement 'If you want further advice on shingles vaccination, please speak to a healthcare professional'. The Panel queried whether it was appropriate to highlight shingles vaccination and encourage members of the public to seek such advice on the homepage, given the need to exercise caution. It might also encourage members of the public to access the health professional material to seek further information about vaccination. On the introductory page to the public section of the website there was also a button marked 'Can shingles be prevented?'. By clicking on that button, readers were told that 'It is possible to prevent shingles. See your GP or other healthcare professionals who can give you more information'.

The first feature on the homepage of the patient organization website was the news item: 'A vaccine for the prevention of shingles is now available. Adults aged 50 and over will be able to have the shingles vaccine (known as Zostavax) through their NHS GP, pharmacist or private healthcare provider'. Readers were told that any registered doctor who believed that the vaccine would benefit a patient was able to prescribe and administer it. The results of two clinical trials were briefly detailed.

In the Panel's view, having read about the possible symptoms and long term effects of shingles, readers

would be keen to avoid developing the disease and to seek ways in which to prevent it. Readers were told that prevention was possible and directed, *inter alia*, to a website which, at the outset, highlighted the availability of Zostavax. The Panel noted its comments above about the emphasis given to prevention in the advertisement, and its view that the website addresses were an integral part of the advertisement and the company's responsibility in that regard. The Panel considered that the advertisement posed the question 'how do you prevent shingles?' and answered that question with the name of the product which was the subject of the first item on the homepage of the patient organisation website. The Panel considered that the combined effect of the advertisement and websites was to promote Zostavax to the general public. A breach of the Code was ruled.

The Panel considered that the material (the advertisement and websites combined) was not balanced. There was a disproportionate emphasis on vaccination, including the name of the vaccine. A breach of the Code was ruled.

The Panel noted its rulings above that high standards had not been maintained. A breach of the Code was ruled.

The Panel did not consider that a ruling of a breach of Clause 2 was warranted. A ruling of a breach of that clause was regarded as a sign of particular censure and reserved for such. The Panel was concerned about the material. Nonetheless, taking all the circumstances into account it considered that its ruling of a breach of the Code above, in that high standards had not been maintained, provided adequate censure and, on balance, ruled no breach of Clause 2.

A doctor complained about an advertisement (ref UK15219n 04/12) placed by Sanofi Pasteur MSD Ltd in City Life Cardiff, Summer 2012.

The advertisement, which was presented in the style of an advertorial, had a 'Shingles Aware' logo in the top left-hand corner. The headline read 'If, like 90% of UK adults, you have ever had chickenpox, there is a 1 in 4 chance you will develop shingles at some point in your lifetime'. The following three paragraphs described the symptoms of shingles and advised the reader about the need to see a GP as soon as possible. Following these paragraphs were the separate statements, in a bolder font, 'It is possible to prevent shingles' and 'See your GP who can give you more information'. Readers were then directed to other information on the shingles aware website (sponsored by Sanofi Pasteur MSD) or an independent patient organization website. Readers could scan a QR Code with a smart phone to access the shingles aware website.

Sanofi Pasteur MSD marketed Zostavax (shingles (herpes zoster) vaccine (live)) indicated for the immunization of the over 50s to prevent herpes zoster (shingles) and herpes zoster-related post-herpetic neuralgia.

COMPLAINT

The complainant was concerned that the advertisement breached the Code.

When writing to Sanofi Pasteur MSD the Authority asked it to consider Clauses 2, 9.1, 22.1 and 22.2 of the Code.

RESPONSE

Sanofi Pasteur MSD stated that shingles (also known as herpes zoster) was a potentially serious condition that could lead to long-term, debilitating complications, such as post-herpetic neuralgia (PHN), which adversely affected patients' quality of daily life. Shingles was caused by reactivation of the varicella zoster virus (VZV), which remained latent after primary infection, ie chickenpox. Although there were many reasons for reactivation, a decline in VZV-specific cell mediated immunity, most commonly due to ageing, was thought to play a major role.

Over 90% of adults raised in the UK were seropositive for VZV and therefore at risk of developing shingles (Department of Health, 2011).

The estimated annual number of herpes zoster cases in England and Wales in the immunocompetent population of 60 years and older was 88,650 (95% credibility intervals 65,000–113,000), of which 18,200 (13,500–23,300) were estimated to remain in pain after 3 months. There were an estimated 1,750 (1,300–2,200) hospitalisations in the 60 plus age group every year, and it was estimated that 55 (54–56) people died with zoster recorded as a cause of death.

Currently herpes zoster and its complications was managed symptomatically and treatment did not address the underlying pathology leading to a clear unmet need in the patient population.

Antiviral therapy was the standard treatment for herpes zoster and shortened the duration of acute herpes zoster. However, there was little evidence to show that it was effective if given more than 72 hours after the onset of the rash. Furthermore, antivirals did not prevent the development of PHN.

PHN was non-resolving and there were no curative therapies. Despite extensive research and development, the analgesics used to treat PHN were not very effective and at best afforded around 50% pain relief for only half of patients treated (Hempenstall *et al*, 2005; Scott *et al* 2003). There was a lack of data on the co-morbidities resulting from pain. People with PHN also suffered from moderate to severe depression and other related co-morbidities affected their quality of life and activities of daily living (Bouhassira *et al*, 2011; Oster *et al*, 2005; van Seventer *et al*, 2006). Lack of sleep was another co-morbidity. PHN occurred predominantly in the elderly (mean age 75 years old) and could therefore tip people into dependency.

Market research conducted on behalf of Sanofi Pasteur MSD in July 2011 to assess patients' understanding of shingles and its sequelae involved a nationally representative selection of UK adults aged 50–79 years. Almost all respondents were aware of shingles, however it was clear from the research that there was a low understanding of the details and a misunderstanding of the severity of the disease, for

example only 10% were aware of PHN. Of particular note was the finding that those individuals who had direct or indirect experience of shingles assigned a much higher severity score to the condition than those who had no experience of the disease. This research indicated an urgent need for disease awareness education in the 50 plus age group who were at particular risk for shingles and its consequences.

The potential seriousness of shingles and its commonest complication of PHN had been recognised by the Joint Committee on Vaccination and Immunisation (JCVI) – a Standing Advisory Committee with the purpose 'To advise the Secretary of State for Health and Welsh Ministers on matters relating to the provision of vaccination and immunisation services, being facilities for the prevention of illness'.

On 29 March 2010, the JCVI issued the following statement on herpes zoster vaccine:

'JCVI reviewed medical, epidemiological, and economic evidence as well as vaccine safety and efficacy data relevant to a herpes zoster (shingles) vaccination programme. Based on the evidence, a universal herpes zoster vaccination programme for adults aged 70 years up to and including 79 years is recommended provided that a licensed vaccine is available at a cost effective price.'

Based on this recommendation and the availability of a vaccine, the Department of Health issued a tender for the shingles vaccine with the aim of commencing a vaccination programme for those aged 70-79 years in 2013.

Sanofi Pasteur MSD contended therefore that, given the significant burden imposed by shingles, a disease awareness campaign benefitted patients and the wider healthcare environment.

Sanofi Pasteur MSD was aware that the Code set standards for the professional, ethical and transparent advertising and promotion of medicines for prescribing to health professionals to ensure the appropriate use of medicines and support the provision of high quality healthcare. With this in mind, it devised a disease awareness programme on shingles and PHN following the JCVI recommendation for a shingles vaccination programme, to coincide with the launch of Zostavax. To underpin this campaign, Sanofi Pasteur MSD used evidence from clinical trials, databases (GPRD) and market research.

Sanofi Pasteur MSD also undertook a due diligence process as it was the only manufacturer of a shingles vaccine. It liaised with the Medicines and Healthcare products Regulatory Agency (MHRA) over promotional materials as well as having many of these materials pre-vetted by the MHRA. Sanofi Pasteur MSD noted the MHRA guidance on disease awareness campaigns which stated that the primary purpose of such a campaign must be to increase the awareness of a disease and to provide health educational information on that disease and its

management. It should not promote the use of a particular medicine or medicines. It further stated that the emphasis should be on the condition and its recognition rather than on treatment options. Sanofi Pasteur MSD submitted that the shingles disease awareness campaign had been pre-vetted by the MHRA and changed on the MHRA's recommendation. This pre-vetting demonstrated that the campaign was compliant with the MHRA disease awareness campaign guidelines. The campaign materials emphasised more the importance of disease recognition, the signs and symptoms of the disease, that the disease was usually mild and resolved without sequelae with prompt treatment, the possible complications and finally mentioning the possibility of prevention without actually stating that there was a vaccine to prevent shingles. Sanofi Pasteur MSD submitted that the disease awareness campaign was fair and balanced.

The advertisement for shingles that was placed in magazines appealed to readers aged 50 years and over, at particular risk of shingles and therefore in need of education on this disease, was written in a style that a lay-person could understand; it avoided medical terminology and provided a clear description of symptoms and the need to seek medical attention urgently if shingles was suspected. There was a simple explanation of the connection between an earlier episode of chickenpox and a later episode of shingles to ensure that the reader recognised that they might be at risk of shingles; this was important as although the market research indicated that many adults associated shingles with chickenpox, there was not universal recognition of this connection. Great care was taken to ensure the facts were not over-exaggerated and that the advertisement would raise awareness of shingles and prompt patients to seek treatment if they developed shingles. The advertisement stated that the symptoms of shingles were usually mild, most people recovered, shingles varied in its presentation, patients should see their GP within 72 hours of the rash occurring, most people did not have any long term effects but serious complications of the eye could occur if shingles developed in the eye. As this was a disease awareness campaign Sanofi Pasteur MSD added a short statement that it was possible to prevent shingles – but did not mention a product.

To further balance the information in the advertisement, Sanofi Pasteur MSD also included the name of a patient support website which could provide further independent information.

Sanofi Pasteur MSD submitted that the information contained in this advertisement formed part of a disease awareness campaign for the public. The aim of the campaign was to provide general information on shingles, the range of presenting symptoms and sequelae related to the disease. In particular, the campaign focused on the need for patients to seek treatment promptly. The description of shingles symptomology emphasised that the acute symptoms of shingles were usually mild and that most people recovered without sequelae.

However, it was important for the public to appreciate that shingles varied in its presentation from person to person both in its acute presentation and also in longer term consequences. It was important for patients with shingles to see their GP within 72 hours of the rash occurring in order to assess the need for antiviral therapy which might inhibit replication of VZV, thereby reducing the duration of viral shedding, increasing rash healing and reducing the severity and duration of pain (Johnson and Dworkin, 2003). There was little evidence to show that antiviral therapy was effective if given more than 72 hours after the onset of the rash. Shingles affecting the eye region (ophthalmic shingles) occurred in 10-20% of shingles patients (Cunningham *et al*, 2008). Without antiviral therapy, 50%-72% of patients with periocular herpes zoster would have involvement of the ocular structures and develop chronic disease; in one study, 20% of patients with herpes zoster uveitis were found to be legally blind in the involved eye (Dworkin *et al*, 2007).

The layout with the image of a woman, with the barbed wire belt representing the pain of shingles, holding a photograph with her younger self suffering from chickenpox, was designed to provide a simple link between childhood chickenpox and later reactivation of the virus leading to shingles. This striking image aimed to trigger a recognition that anyone who had suffered from chickenpox might be at risk of shingles and therefore should be aware of the need to seek urgent medical attention should symptoms arise.

Sanofi Pasteur MSD stated that because of the range of severity of symptoms, the advertisement was careful not to exaggerate the symptoms experienced by most people with shingles; 'the symptoms of shingles are usually mild but can be very unpleasant for some'. PHN was described as part of the spectrum of complications but it was made clear that most people recovered without sequelae.

The MHRA guidance stated that an important aspect of any health promotion campaign was to raise awareness of the symptoms so that members of the public could seek early diagnosis and treatment, minimise disease progression or avoid complications. The shingles campaign aimed to raise awareness of the need for medical attention within 72 hours of appearance of the rash in order that the GP could assess the need for antiviral treatment. This timing was critical as there was little evidence to show that antiviral therapy was effective if given more than 72 hours after the onset of the rash.

Sanofi Pasteur MSD submitted that a vaccine was available indicated for the prevention of herpes zoster and post-herpetic neuralgia in individuals aged 50 years and over. A discussion of shingles in the 50 plus age group would not be complete or balanced without an indication that a means of prevention was available. Prevention was mentioned within the context of disease awareness because there was a vaccine indicated for the prevention of herpes zoster and PHN in individuals aged 50 years and over (Zostavax). This indication was put into the context of disease management and formed a minor part of the disease awareness messages. There was no mention of vaccination and

neither the brand name nor the generic name of the vaccine were included in the advertisement. Sanofi Pasteur MSD asserted, therefore, that the advertisement was not in breach of Clause 22.2. It was part of a *bona fide* disease awareness campaign as described in the supplementary information to Clause 22.2. Sanofi Pasteur MSD had taken care to ensure that the disease information provided in the advertisement was fair and balanced. There was no mention of specific products, thus there were no statements made for the purpose of encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine. Sanofi Pasteur MSD asserted it had also complied with the MHRA's guidance on disease awareness campaigns in that the primary purpose of its campaign was to increase awareness of shingles and to provide information on shingles and its management and that it did not promote the use of a particular medicine. Sanofi Pasteur MSD worked closely with the MHRA to ensure this fair balance.

Sanofi Pasteur MSD submitted that the need to obtain medical attention was not accompanied by any recommendations for treatment as these would be determined by the GP according to individual patient need. There was no mention of vaccination and neither the brand name nor the generic name of the vaccine were contained in the advertisement.

Sanofi Pasteur MSD submitted that it always strove to maintain the highest standards in all its activities. It was the only manufacturer of a vaccine licensed to prevent shingles. As such it recognised that it had an onus in its disease awareness campaign to focus on disease education and provide details of where to get appropriate advice. The company submitted that the advertisement in question fulfilled this in a fair and balanced manner. The advertisement raised the awareness of shingles as a potentially serious disease but stated that most cases were mild and recover, that the presentation of shingles was variable and so some patients might need treatment – treatment was not specified as the patient consultation with the GP would decide appropriate treatment which might include options apart from medicines, that patients should see their GP within 72 hours of a rash appearing, that most people did not have any long term effects and warned that if shingles affected the eye serious complications of the eye could occur. The advertisement also stated that it was possible to prevent shingles and that the patient should contact their GP for more information.

Hence in maintaining high standards, Sanofi Pasteur MSD considered that the information was accurate, up-to-date, capable of substantiation, comprehensive, balanced, fair and readable.

Sanofi Pasteur MSD stated that it had not prejudiced patient safety and/or public health. There had been no inducements to prescribe. No product had been mentioned in the advertisement. As part of the disease awareness campaign prevention had had only one mention and Sanofi Pasteur MSD asserted that this was entirely reasonable given that the vast majority of content related to disease and treatment.

In summary, Sanofi Pasteur MSD asserted that, given the significant burden imposed by shingles, a disease awareness campaign was of benefit to patients and the wider healthcare environment. Sanofi Pasteur MSD also believed this disease awareness campaign was fair and balanced.

Sanofi Pasteur MSD asserted that the advertisement was not in breach of Clause 22.2 of the Code. It formed part of a *bona fide* disease awareness campaign as described in the supplementary information to Clause 22.2.

Sanofi Pasteur MSD had taken care to ensure that the disease information provided in the advertisement was fair and balanced. Sanofi Pasteur MSD therefore considered that the advertisement formed part of a *bona fide* disease awareness campaign and did not constitute an advertisement of a prescription only medicine to the public and was not in breach of Clause 22.1.

Sanofi Pasteur MSD also considered that the information was accurate, up-to-date, capable of substantiation, comprehensive, balanced and fair, high standards had been maintained and there was therefore no breach of Clause 9.1.

Sanofi Pasteur MSD stated that this advertisement had not prejudiced patient safety and/or public health. Taking into account Sanofi Pasteur MSD's reasoning for its shingles disease awareness campaign and its justification for the advertisement in question, Sanofi Pasteur MSD therefore submitted that there had been no breach of Clause 2.

PANEL RULING

The Panel noted that the supplementary information to Clause 22.2, Information to the Public, stated that a company could conduct a disease awareness campaign provided that the purpose was to encourage the public to seek treatment for symptoms while in no way promoting the use of a specific medicine. It was stated that particular care must be taken where the company's product, even though not named, was the only medicine relevant to the disease or symptoms.

The Panel noted that with regard to the shingles awareness campaign, Zostavax, a vaccine recently launched by Sanofi Pasteur MSD, was the only medicine for the prevention of shingles. The vaccine was only for use in patients aged 50 years or more.

The Panel noted that the headline to the advertisement in question told the reader that 90% of UK adults had a 1 in 4 chance of developing shingles. The following three paragraphs of text informed the reader that shingles occurred more frequently in those aged 50 years or more and then went on to describe the symptoms of shingles. Although the reader was told that symptoms were 'usually mild', they could be 'very unpleasant for some'. The pain associated with shingles was described as 'burning' and might be 'extreme' and that after 'painful blisters burst' and crusted over some people would continue to feel 'extreme pain' that could continue for 'many

months' or 'even years'. Readers were further told that this pain could 'prevent sufferers from living a normal life' and that the lightest touch to the skin could be 'painful and distressing'. Shingles varied from person to person and some people would require treatment. Readers were advised to seek medical help within 72 hours of developing a rash and that if shingles developed in the eye it could lead to 'decreased vision or even permanent blindness'.

The Panel noted that following the paragraphs which described the symptoms of shingles, the statement 'It is possible to prevent shingles' appeared in bolder, darker and thus more prominent font. This statement was clearly separated from the previous text and in that regard the Panel considered that the reader's eye would be drawn to it. This statement was followed by a separate equally prominent statement 'See your GP who can give you more information'. The prominence, font colour and position of the statement was such that some readers would associate it particularly with the preceding statement and conclude that their GP could provide more information particularly on the prevention of shingles. The Panel's view was that the final 'take home' message from the advertisement was one of prevention.

The Panel noted that whilst disease awareness was in principle a legitimate and helpful activity, caution should be exercised when there was only one product available. Whilst the advertisement discussed symptoms and some relatively rare but serious consequences of shingles, there was very little discussion of treatment. The emphasis, as described above, was on prevention. The Panel queried whether it was sufficiently balanced in this regard given the need to exercise caution.

The Panel noted that the supplementary information to Clause 24.6, Sites Linked via Company Sites, stated that such sites were not necessarily covered by the Code. The Panel noted that Clause 24.6 applied to links from a company website (rather than hard copy material) to another site and thus was not directly applicable to the circumstances of this case. Nonetheless, the Panel noted that whether a linked site came within the scope of the Code had to be decided on a case by case basis. The Panel considered that companies that published website addresses as an integral part of 'the message' of their material as in the present case, and directed the public to seek further information about that message from such sites needed to be satisfied that the website content was reasonable as far as the Code was concerned. This was so whether or not they had any input to, or ability to, influence the content. If this were not the case then companies would be able to refer to independent sites as a means of circumventing the Code.

Readers were directed to two websites; the company-sponsored shingles aware website and an independent patient organization website. On the home page of the shingles aware website there were two separate buttons; one marked 'Information for the public' and the other marked 'Information for healthcare professionals'. Below the 'Information for

the public' button was the statement 'If you want further advice on shingles vaccination, please speak to a healthcare professional'. The Panel queried whether it was appropriate to highlight shingles vaccination and encourage members of the public to seek such advice on the homepage, given the need to exercise caution. It might also encourage members of the public to access the health professional material to seek further information about vaccination. On the introductory page to the public section of the website there was also a button marked 'Can shingles be prevented?'. By clicking on that button, readers were told that 'It is possible to prevent shingles. See your GP or other healthcare professionals who can give you more information'.

The first feature on the home page of a patient organization website was the following news item: 'A vaccine for the prevention of shingles is now available. Adults aged 50 and over will be able to have the shingles vaccine (known as Zostavax) through their NHS GP, pharmacist or private healthcare provider'. Readers were told that any registered doctor who believed that the vaccine would benefit a patient was able to prescribe and administer it. The results of two clinical trials were briefly detailed.

In the Panel's view, having read about the possible symptoms and long term effects of shingles, readers would be keen to avoid developing the disease and to seek ways in which to prevent it. Readers were told that prevention was possible and directed, *inter alia*, to a website which, at the outset, highlighted the availability of Zostavax. The Panel noted its comments above about the emphasis given to prevention in the advertisement, and its view that the website addresses were an integral part of the advertisement and the company's responsibility in

that regard. The Panel considered that the advertisement posed the question 'how do you prevent shingles?' and answered that question with the name of the product which was the subject of the first item on the homepage of the patient organisation website. The Panel considered that the combined effect of the advertisement and websites was to promote Zostavax to the general public. A breach of Clause 22.1 was ruled.

The Panel considered that the material (the advertisement and websites combined) was not balanced. There was a disproportionate emphasis on vaccination, including the name of the vaccine, such that the caution urged by the relevant supplementary information to Clause 22.2 had not been exercised. The Panel noted its ruling of a breach of Clause 22.1 above and ruled a breach of Clause 22.2.

The Panel noted its rulings above that high standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel did not consider that a ruling of a breach of Clause 2 was warranted. A ruling of a breach of that clause was regarded as a sign of particular censure and reserved for such. The Panel was concerned about the material. Nonetheless, taking all the circumstances into account it considered that the ruling of a breach of Clause 9.1 provided adequate censure and, on balance, ruled no breach of Clause 2.

Complaint received	25 July 2012
Case completed	28 September 2012