CASE AUTH/3394/10/20

ANONYMOUS HEALTH PROFESSIONAL v NOVARTIS

Disease awareness campaign

An anonymous, non-contactable complainant who described him/herself as a health professional, complained about a patient information booklet about melanoma, 'Melanoma. Let's get under the skin of it', available on the Novartis Pharmaceuticals UK Ltd website. Novartis marketed Tafinlar (dabrafenib) and Mekinist (trametinib) for use in certain melanoma patients with a BRAF V600 mutation.

The complainant noted that the booklet in question had been produced in association with Melanoma UK [a patient support organisation]. A section about 'Therapy options' included the statement '*Testing for a mutation to the BRAF gene is the only way you can know if targeted therapy is an option for you. Once your doctor knows if you have the BRAF mutation, you can begin to discuss targeted therapy as a treatment option*.' The complainant noted other references to the BRAF gene and targeted therapies in the 'Summary' and in that regard was concerned that Novartis was indirectly pointing to its own medicine and trying to get patients to ask for targeted therapies. In reality, even if patients had a BRAF mutation it did not mean they would be prescribed that targeted therapy; it was not the only treatment option.

The complainant further noted that a woman running around in the sunshine was not a great picture for melanoma – and should not imply patients were fine to do that once treated. The complainant stated that he/she could not work out how Melanoma UK was involved in this booklet, he/she did not believe 'in association with' gave a clear picture of both parties' involvement and wondered why Melanoma UK would advocate that approach.

The detailed response from Novartis is given below.

The Panel noted Novartis' submission that the booklet was one of a number of materials produced in 2019 as part of a disease awareness campaign aimed at patients and carers.

The Panel noted that while the Code prohibited the advertising of prescription only medicines to the public it permitted information to be made available to the public about such medicines provided the information was factual and presented in a balanced way. Information must not raise unfounded hopes of successful treatment or be misleading with respect to the safety of the product. Statements must not be made for the purpose of encouraging a member of the public to ask their health professional to prescribe a specific prescription only medicine. The Panel noted that the supplementary information to the Code stated that a company might conduct a disease awareness or public health campaign provided that the purpose was to encourage members of the public to seek treatment for their symptoms while in no way promoting the use of a specific medicine. The use of brand or non-proprietary names and/or restricting the range of treatments

described in the campaign might be likely to lead to the use of a specific medicine. Particular care must be taken where the company's product, even though not named, was the only medicine relevant to the disease or symptoms in question.

The Panel noted that the booklet had been developed to provide those who had recently been diagnosed with melanoma with information about melanoma gene mutations – in particular the BRAF gene – and the relevance of those mutations in making treatment decisions. The booklet stated that knowing whether you had a mutation to the BRAF gene could help patients better understand their available treatment options and that getting tested to see if their melanoma was BRAF positive was simple and the results might expand their treatment options. The section 'Who should be tested for BRAF and why' further stated that medicines that targeted mutations in the BRAF gene were available and had been shown to be effective in treating melanoma. The 'Therapy options' section discussed surgery and in particular targeted therapies and immunotherapies in relation to BRAF positive patients. The Panel noted Novartis' submission that there were currently seven targeted treatments available including two from Novartis and five from two other pharmaceutical companies.

The Panel did not consider that the information in the booklet failed to meet the requirements of the Code. In the Panel's view, the information was balanced and would not encourage a member of the public to ask their health professional to prescribe a specific prescription only medicine. The material might lead a member of the public to ask about being tested for the BRAF gene mutation so that available treatment options could be considered, which included, but was not limited to, Novartis' medicines. No breach of the Code was ruled.

Given its rulings above the Panel considered that high standards had been maintained and it ruled no breaches of the Code including of Clause 2.

The Panel noted the complainant's allegation that the photograph of a woman running around in the sunshine was inappropriate for melanoma patients. There were four images within the booklet and the Panel considered that the complaint was about the image on page two which depicted a lady walking through a field of long grass, on what appeared to be a sunny day, wearing a long sleeved top and trousers, but no hat.

The Panel noted Novartis' submission that published NHS advice stated 'the most common sign of melanoma is the appearance of a new mole or a change in an existing mole. This can happen anywhere on the body, but the most commonly affected areas are the back in men and the legs in women'. Novartis noted that the back and legs were areas covered by clothing in the image in question. According to Novartis, individuals with melanoma were not generally expected to entirely avoid the outdoors; it was recommended that they 'cover up with suitable clothing'. The NHS website also advised patients to 'aim to strike a balance between protecting yourself from the sun and getting enough vitamin D from sunlight'. The Panel noted Novartis' submission that all of the images in the booklet were appropriate for the melanoma population. Whilst the Panel acknowledged that most patients with melanoma would not entirely avoid being outdoors, it was concerned that the woman in the image was not wearing a hat given that melanoma could occur anywhere on the body. However, and on balance, the Panel did not consider that the image implied that patients with melanoma were fine to be out in the sunshine once treated as alleged. No breach of the Code was ruled.

The Panel noted that the Code stated, *inter alia*, that when working with patient organisations, companies must ensure that their involvement was made clear and that all of the arrangements complied with the Code. That included the need for companies to clearly acknowledge their sponsorship from the outset.

The front page of the booklet stated 'This material was developed by Novartis Pharmaceuticals UK Ltd, in association with Melanoma UK.' The Panel noted Novartis' submission that it had engaged with Melanoma UK in order to ensure the educational materials were of a high standard and appropriate for the melanoma population; Melanoma UK had the opportunity to perform an 'offline review' of all materials involved in the disease awareness campaign and had, in turn, endorsed the booklet and the wider campaign. The letter of agreement between the parties, written by Novartis and signed by Melanoma UK, appeared to be about the use of the Melanoma UK logo and Melanoma UK's involvement in the campaign. It was stated that Melanoma UK would be named as a campaign partner on all the materials and that it would make those materials available on its website.

The Panel noted that it did not appear that Novartis had sponsored Melanoma UK material but rather that Melanoma UK had reviewed, endorsed and would make available on its website, Novartis material. In the Panel's view the requirement to declare sponsorship was not relevant and no breach was ruled.

The Panel noted the complainant's submission that he/she could not work out how Melanoma UK was involved in this booklet and his/her view that 'in association with' did not give a clear picture of both parties' involvement. The Panel considered that when deciding whether the involvement of Novartis was clear on the material, the description of the role of Melanoma UK was relevant as was the nature of the intended audience. The Panel noted Novartis' submission that the disclaimer 'in association with' was commonly used by pharmaceutical companies when patient groups endorsed public facing materials. The Panel disagreed with Novartis' submission that it was synonymous with 'developed with', 'in collaboration with', 'in partnership with', etc and that it clearly indicated who was involved with the materials.

The Panel noted that the booklet was intended for the public and considered that the statement 'This material was developed by Novartis Pharmaceuticals UK Ltd, in association with Melanoma UK' was ambiguous; to some it might imply that Melanoma UK was involved in the development/creation of the material which was not so. Novartis' agreement with Melanoma UK stated that Melanoma UK would be named as a campaign partner on the materials and would make the materials available on its website. In the Panel's view it was particularly important that company materials on a patient organisation's website accurately stated the role and input of each party. On balance the Panel considered that the description of each party's role in relation to the material, particularly the use of 'in association with', was ambiguous and thereby misleading such that the role of the company was unclear; a breach of the Code was ruled.

An anonymous, non-contactable complainant who described him/herself as a health professional complained about a patient information booklet about melanoma, 'Melanoma. Let's get under the skin of it' (ref ONC19-C049b(1)), available on the Novartis Pharmaceuticals UK Ltd website. Novartis marketed Tafinlar (dabrafenib) and Mekinist (trametinib) which were used in certain melanoma patients with a BRAF V600 mutation.

COMPLAINT

The complainant noted that the booklet had been produced in association with Melanoma UK [a patient support organisation] and that page 10 [under the heading 'Therapy options'] stated:

> 'Testing for a mutation to the BRAF gene is the only way you can know if targeted therapy is an option for you. Once your doctor knows if you have the BRAF mutation, you can begin to discuss targeted therapy as a treatment option.'

and page 11 [in the 'Summary'] stated:

> '- Depending on the type of melanoma and stage of the disease, your cancer may be treated with surgery, radiation therapy, and/or drug therapy
>
> - A biomarker for melanoma (the BRAF mutation) has been identified for which targeted therapies are available
>
> - If you have tested positive for a mutation to the BRAF gene, your doctor may discuss with you available targeted therapies that may help fight your tumour'

The complainant was concerned that Novartis was indirectly pointing to its own medicine and trying to get patients to ask for targeted therapies. In reality, even if patients had a BRAF mutation it did not mean they would be prescribed that targeted therapy; that was not the only treatment option.

The complainant further noted that a woman running around in the sunshine was not a great picture for melanoma – and should not imply patients were fine to do that once treated. The complainant stated that he/she could not work out how Melanoma UK was involved in the booklet and did not consider that 'in association with' gave a clear picture of both parties' involvement and wondered why Melanoma UK would advocate that approach.

When writing to Novartis, the Authority asked it to consider the requirements of Clauses 27.9, 27.2, 26.2, 9.1, 7.6 and 2 of the Code.

RESPONSE

Novartis explained the booklet, 'Melanoma. Let's get under the skin of it / Understanding the BRAF mutation' (copy provided) was hosted on a public facing Novartis website and was one of a number of materials produced in 2019 as part of a disease awareness campaign aimed at melanoma patients and their carers. The campaign was funded by Novartis UK and supported by Melanoma UK, a charity with the vision 'to increase the UK's awareness of melanoma and its prevention through advocacy, education and research'. The aim of the campaign was to provide patients and their carers with information on the condition, and to encourage those diagnosed with melanoma to discuss the various treatment options with their health professionals. More specifically, the guide was developed to provide those who had recently been diagnosed with melanoma with information about melanoma gene mutations, particularly the BRAF gene, and its relevance with regard to making treatment decisions.

Novartis explained that melanoma was the most aggressive form of skin cancer. Worldwide, it was expected that over 232,000 people would be diagnosed with the condition each year and

more than 55,000 people were expected to die from it annually. In Europe, over 106,000 cases of melanoma were newly diagnosed and over 16,000 patients died from it in 2020. In the UK 1 in 36 men and 1 in 47 women would be diagnosed with melanoma during their lifetime. There were around 2,400 melanoma skin cancer deaths in the UK every year; more than 6 every day. Over the last decade, rates of melanoma skin cancer had increased by 50% in the UK; rates in men had increased by almost 64% and rates in women had increased by almost 39%.

Novartis stated that BRAF was a particularly important genomic target that might affect melanoma treatment options and outcomes. BRAF mutations occurred frequently as a melanoma disease driver (the mutation caused cells to grow and divide too quickly). Approximately 40-50% of melanoma patients had a mutation to the BRAF gene and so it was an important factor to highlight in educational content. Educating patients and health professionals encouraged the identification of the mutation which would expand treatment choices for identified patients.

Melanoma was often diagnosed at an early stage when surgical excision was curative in most cases. Patients who were at a high risk of developing metastatic disease might benefit from adjuvant therapy. The management of patients with unresectable or metastatic melanoma was more difficult, although recent advances in treatment had led to important improvements of clinical outcomes for that population. Treatment options for those patients included immunotherapy with immune checkpoint inhibitors and/or targeted therapy that inhibited the mitogen-activated protein kinase (MAPK) pathway for BRAF V600 mutant melanoma.

The melanoma section of the NHS website stated that 'If melanoma is not diagnosed until an advanced stage, treatment is mainly used to slow the spread of the cancer and reduce symptoms. This usually involves medicines that target specific genetic changes in the melanoma, such as BRAF inhibitors, or medicines that boost your body's immune responses to the melanoma'. In addition, patient groups, such as Cancer Research UK and Macmillan Cancer Support had content on their websites which highlighted the BRAF gene as an important mutation to test for because it might impact on treatment decisions. That was why Novartis, in association with Melanoma UK, had produced the booklet in question so that patients could better understand that.

Novartis submitted that the booklet was relevant to all patients who had been diagnosed with melanoma, regardless of severity, duration and treatment history. The aim was to provide factual information on the condition, help patients to understand more about their disease and encourage them to discuss appropriate treatment options with their health professionals.

The booklet outlined a range of treatment options in a factual, balanced and complete way without raising unfounded hopes of successful treatment. That included understanding the role of gene mutations in treatment decisions, which was aligned with the above advice from patient groups and the NHS, as well as the National Institute for Health and Care Excellence (NICE) and Melanoma UK.

Novartis submitted that the booklet did not refer to particular products, nor was there any intention to encourage members of the public to ask their health professionals to prescribe particular prescription only medicines.

Novartis commented as follows on a number of quotations from the booklet which it submitted demonstrated that information was being shared in a fair and balanced way:

'It is important to talk to your doctor about getting tested for the mutation to the BRAF gene as soon as possible after diagnosis. Once you know if you have this mutation, you and your doctor will be better informed to explore treatment options.'

Novartis noted that this was the rationale for BRAF mutation testing ie it helped the patient and doctor to make an informed choice.

Novartis noted that BRAF mutation testing might expand treatment options for patients who were BRAF positive, providing more choices. BRAF positivity was seen in up to 40-50% of melanoma patients. BRAF testing would also inform when a patient was BRAF negative and therefore not eligible for BRAF targeted treatment; this was also an important outcome that could inform the treatment decision.

'Melanoma is classified by clinical stages 1, 2, 3 and 4, on the basis of the extent of the disease. Depending on the stage of the melanoma, there are a range of treatment options, including surgery, radiation therapy, and drug therapy.'

Novartis submitted that this statement explained the broad and balanced treatment options, both pharmacologic and non-pharmacologic, available to a patient dependent on their disease stage.

'Multiple gene mutations can play a role in the progression of melanoma. The three most common mutations in melanoma are to the BRAF, NRAS and c-KIT genes. However, the only mutation for which targeted therapy is available is for the BRAF gene.'

This statement clarified the three most common mutations in melanoma. However, BRAF was the only one where a treatment option was available – this was a factual statement. Further, there were a number of BRAF targeted therapies available, none were named specifically in this material.

'*Getting tested to see if your melanoma is BRAF positive is simple and getting these test results may expand your treatment options.'*

Novartis submitted that patients who tested positively for the BRAF mutation had additional options whilst those who tested negatively would not be offered targeted therapy.

'There are two types of drugs used to treat advanced melanoma: targeted therapies and immunotherapies' and 'Immunotherapies can be effective against both BRAF positive and BRAF wild-type advanced melanomas'

Novartis submitted that this statement highlighted both targeted and non-targeted therapies. The chart provided on the same page showed a balanced comparison.

This was evidence of a balanced presentation of targeted and non-targeted treatment options, without bias towards targeted therapies. Immunotherapy was featured as an option for BRAF positive patients, as well as the targeted therapies available.

'*Testing for a mutation to the BRAF gene is the only way you can know if targeted therapy is an option for you. Once your doctor knows if you have the BRAF mutation, you can begin to discuss targeted therapy as a treatment option.'*

Novartis noted that BRAF testing might expand options for patients. This did not imply that other treatments (defined also) were not also valid options. The goal was to expand treatment options so that the physician and patient could discuss an appropriate treatment plan.

Overall Novartis submitted that the message of the booklet was that patients with melanoma might have options. If a patient was BRAF positive, there were targeted therapies available as well as non-targeted therapies. Health professionals might be aware of the multiple targeted treatments available, but none of those were named in in the booklet. There were no references to any Novartis products, and the information provided was general, not specific. Novartis gave brief details of the targeted treatments currently available. included:

Novartis noted that the supplementary information to Clause 26 of the Code stated that 'A company might conduct a disease awareness or public health campaign provided that the purpose was to encourage members of the public to seek treatment for their symptoms while in no way promoting use of a specific medicine.' Novartis considered that that statement accurately reflected the purpose of the campaign and that the campaign was fully aligned with the guidance provided by the Code. For the reasons stated above, Novartis strongly believed that no elements of the booklet breached Clause 26.2.

Novartis noted that the complainant had commented about the image of 'a woman running round in the sunshine….'. Whilst Novartis assumed that that referred to the image on page 2 of the booklet, the company considered that that and every other image in the booklet conveyed an appropriate message. All individuals were wearing normal, full length clothes covering the majority of their bodies, leaving only traditionally exposed areas such as the face, hands and feet uncovered. Published NHS advice stated that 'the most common sign of melanoma is the appearance of a new mole or a change in an existing mole. This can happen anywhere on the body, but the most commonly affected areas are the back in men and the legs in women'. Novartis noted that the back and legs were areas covered by clothing in the images.

Novartis stated that it was not generally expected that individuals with melanoma should entirely avoid the outdoors; it was recommended that they 'cover up with suitable clothing'. The NHS website also advised patients to 'aim to strike a balance between protecting yourself from the sun and getting enough vitamin D from sunlight'. Novartis considered that the images were appropriate for the melanoma population. Novartis added that when it was being developed, Melanoma UK was consulted and conducted an 'offline review' of the booklet; the images were considered appropriate and Melanoma UK did not raise any concerns.

Novartis noted that it had been asked to 'bear in mind... Clause 7.6 with regard to the complaint about the photograph of a woman'. Clause 7.6 stated that 'when promotional material referred to published studies, clear references must be given'. Novartis was unsure how Clause 7.6 was relevant to the images and requested that that was clarified so that the company might respond appropriately. Notwithstanding that point, for the reasons stated above, Novartis did not believe that the images in the booklet were in breach of any clause of the Code.

Novartis noted that the complainant had stated that he/she 'could not work out how Melanoma UK was involved in this booklet' and that 'in association with' did not give 'a clear picture of both parties' involvement'.

Novartis submitted that the disclaimer 'in association with' was commonly used by pharmaceutical companies and patient groups on public facing materials, when patient groups

endorsed those materials; it was synonymous with 'developed with', 'in collaboration with', 'in partnership with', etc. Those phrases clearly indicated who was involved with the materials and Novartis submitted that a statement in large font at the top of the first page of the booklet was sufficiently clear to any member of the public as to Melanoma UK's involvement; it was also acceptable to Melanoma UK.

Novartis stated the Agreement between Novartis and Melanoma UK provided further detail. Clause 2 of the Agreement provided context in relation to the disease awareness campaign and Clause 6 encouraged transparency in accordance with requirements of the Code. Finally, Clause 8 was evidence that the arrangement was not an intention to inappropriately induce or influence in any way.

Novartis stated that the complainant had questioned 'why Melanoma UK would advocate this approach'. Whilst Novartis could not speak on behalf of Melanoma UK, the company noted the signed Agreement as evidence of the organisation's agreement to that approach. Furthermore, Melanoma UK had posted the material on its website (link provided) which was further proof of its endorsement.

Novartis submitted that it had acted in accordance with, and strongly denied any breaches of, Clause 27.2 and 27.9. The association between Novartis and Melanoma UK was made clear from the outset on the material, as well as recorded in an Agreement between the parties. Melanoma UK had the opportunity to perform an 'offline review' of all materials involved in the disease awareness campaign. The wording 'in association with' therefore accurately reflected the nature of the involvement of both parties.

Novartis submitted that the booklet was created and disseminated with appropriate intentions, in line with the guidance of the Code relating to disease awareness campaigns. Specifically, the intention of the material was to educate melanoma patients on their condition and treatment options, and to encourage them to discuss both with their health professionals.

Novartis stated that it engaged with Melanoma UK in order to ensure the educational materials developed for the public were of a high standard and appropriate for the melanoma population. Melanoma UK had, in turn, endorsed the booklet and the wider campaign. Novartis believed that high standards had been maintained at all times and it denied a breach of Clause 9.1.

Novartis submitted that the booklet was not a material associated with the promotion of any medicines. The Zinc job type 'non promotional/educational materials – patient and public' reflected the intention of the material and for the reasons explained the content contained no promotional language. There was nothing in the booklet that brought discredit upon, or reduced confidence in, the pharmaceutical industry. Further, Novartis believed that, in respect of the campaign, nothing about the relationship between Novartis and Melanoma UK brought discredit upon, or reduced confidence in the pharmaceutical industry. Novartis thus denied a breach of Clause 2 of the Code.

PANEL RULING

The Panel noted Novartis' submission that the 'Melanoma. Let's get under the skin of it. Understanding the BRAF mutation' booklet was one of a number of materials produced in 2019 as part of a disease awareness campaign aimed at melanoma patients and their carers.

The Panel noted that Clause 26.1 prohibited the advertising of prescription only medicines to the public. Clause 26.2 permitted information to be made available to the public about prescription only medicines provided such information was factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading with respect to the safety of the product. Statements must not be made for the purpose of encouraging a member of the public to ask their health professional to prescribe a specific prescription only medicine. The Panel noted that the supplementary information to Clause 26.2 stated that a company might conduct a disease awareness or public health campaign provided that the purpose was to encourage members of the public to seek treatment for their symptoms while in no way promoting the use of a specific medicine. The use of brand or non-proprietary names, and/or restricting the range of treatments described in the campaign might be likely to lead to the use of a specific medicine. Particular care must be taken where the company's product, even though not named, was the only medicine relevant to the disease or symptoms in question.

The Panel noted that the booklet stated that it had been developed to provide those who had recently been diagnosed with melanoma with information about melanoma gene mutations – in particular, to the BRAF gene – and the relevance of those mutations in making treatment decisions. The booklet stated that knowing whether you had a mutation to the BRAF gene could help patients better understand their available treatment options and that getting tested to see if their melanoma was BRAF positive was simple and the results might expand their treatment options. The section 'Who should be tested for BRAF and why' further stated that medicines that targeted mutations in the BRAF gene, known as BRAF inhibitors, were available and had been shown to be effective in treating melanoma. The 'Therapy options' section discussed surgery and in particular targeted therapies and immunotherapies in relation to BRAF positive patients. The Panel noted Novartis' submission that there were seven targeted treatments currently available; two from Novartis and five from two other companies.

The Panel did not consider that the booklet failed to meet the requirements of Clause 26.2 of the Code. In the Panel's view, the information provided was balanced and would not encourage a member of the public to ask their health professional to prescribe a specific prescription only medicine. The material might lead a member of the public to ask about being tested for the BRAF gene mutation so that available treatment options could be considered, which included but was not limited to Novartis' medicines. No breach of Clause 26.2 was ruled.

Given its rulings above the Panel considered that there could be no breach of Clauses 2 and 9.1 of the Code on this matter and ruled accordingly.

The Panel noted that the case preparation manager had raised Clause 7.6 which stated that when promotional material refers to published studies, clear references must be given. The Panel noted the complainant's allegation that the photograph of a woman running around in the sunshine was inappropriate for melanoma patients and that it might imply that patients were able to do so once treated. The Panel considered that Clause 7.8 was the relevant clause which covered artwork needing to comply with the Code. The Panel noted Novartis' submission about the applicability of Clause 7.6 and its detailed comments about the acceptability of the images in relation to the requirements of the Code. Taking all of the circumstances into account, the Panel decided to rule on this matter in relation to the requirements of Clause 7.8 noting that Novartis' detailed comments appeared to cover the complainant's concerns.

The Panel noted that the booklet contained four photographic images and considered that the complaint was in relation to the image on page two which depicted a lady walking through a field of long grass, on what appeared to be a sunny day, wearing a long sleeved top and trousers, but no hat.

The Panel noted Novartis' submission that published NHS advice stated 'the most common sign of melanoma is the appearance of a new mole or a change in an existing mole. This can happen anywhere on the body, but the most commonly affected areas are the back in men and the legs in women'. Novartis noted that the back and legs were areas covered by clothing in the image in question. According to Novartis, individuals with melanoma were not generally expected to entirely avoid the outdoors; it was recommended that they 'cover up with suitable clothing'. The NHS website also advised patients to 'aim to strike a balance between protecting yourself from the sun and getting enough vitamin D from sunlight'. The Panel noted Novartis' submission that all of the images in the booklet were appropriate for the melanoma population. Whilst the Panel acknowledged that most patients with melanoma would not entirely avoid being outdoors, it was concerned that the woman in the image was not wearing a hat given that melanoma could occur anywhere on the body. However, and on balance, the Panel did not consider that the image implied that patients with melanoma were fine to be out in the sunshine once treated as alleged. No breach of Clause 7.8 was ruled.

The Panel noted that Clause 27.2 stated, *inter alia*, that when working with patient organisations, companies must ensure that their involvement was made clear and that all of the arrangements complied with the Code. This included the need to declare sponsorship (Clause 27.9). Clause 27.9 stated that companies must ensure that their sponsorship was always clearly acknowledged from the outset.

The front page of the booklet stated 'This material was developed by Novartis Pharmaceuticals UK Ltd, in association with Melanoma UK.' The Panel noted Novartis' submission that it had engaged with Melanoma UK in order to ensure the educational materials developed for the public were of a high standard and appropriate for the melanoma population; Melanoma UK had the opportunity to perform an 'offline review' of all materials involved in the disease awareness campaign and had in turn endorsed the booklet and the wider campaign. The Panel noted that the letter of agreement between Novartis and Melanoma UK, written by Novartis and signed by Melanoma UK, appeared to be regarding the use of the Melanoma UK logo on the disease awareness campaign materials and Melanoma UK's involvement in the campaign. It was stated that Melanoma UK would be named as a campaign partner on all the campaign materials and that it would make those materials available on its website.

The Panel noted that it did not appear that Novartis had sponsored Melanoma UK material but rather that Melanoma UK had reviewed, endorsed and would make available on its website Novartis material. In the Panel's view Clause 27.9 was not relevant and no breach was ruled.

The Panel noted the complainant's allegation that he/she could not work out how Melanoma UK was involved in the booklet and did not believe 'in association with' gave a clear picture of both parties' involvement. The Panel considered that when deciding whether the involvement of Novartis was clear on the material at issue as required by Clause 27.2, the description of the role of Melanoma UK was relevant as was the nature of the intended audience. The Panel noted Novartis' submission that the disclaimer 'in association with' was commonly used by pharmaceutical companies and patient groups on public facing materials, when patient groups endorsed those materials. The Panel disagreed with Novartis' submission that it was

synonymous with ‘developed with’, ‘in collaboration with’, ‘in partnership with’, etc and that it clearly indicated who was involved with the materials.

The Panel noted that the booklet was intended for the public and considered that the statement ‘This material was developed by Novartis Pharmaceuticals UK Ltd, in association with Melanoma UK’ was ambiguous. In the Panel’s view some members of the public might consider that it implied an involvement of Melanoma UK in the actual development/creation of the material whilst others might consider that there was no such involvement but that it had been developed by Novartis and Melanoma UK had only reviewed and endorsed the content and had agreed for its name to appear on the material. In the Panel’s view the latter implication was consistent with Novartis’ response. Novartis’ agreement with Melanoma UK stated that Melanoma UK would be named as a campaign partner on the materials and would make the materials available on its website. In the Panel’s view, it was particularly important that company materials on a patient organisation’s website accurately stated the role and input of each party. On balance the Panel considered that the description of each of the parties’ role in relation to the material particularly in relation to use of the term ‘in association with’ was ambiguous and thereby misleading such that the role of the company was unclear; a breach of Clause 27.2 was ruled.

Complaint received **4 October 2020**

Case completed **22 March 2021**