ANONYMOUS, NON-CONTACTABLE v BRISTOL-MYERS SQUIBB

Alleged pre-licence promotion of Opdivo

An anonymous non-contactable complainant complained about the conduct of Bristol-Myers Squibb Pharmaceuticals in relation to Opdivo (nivolumab). The complainant stated that he/she was a consultant oncologist and haematologist working in the UK and referred to two incidents.

Opdivo was licensed for the treatment of certain cancers, these being melanoma, non-small cell lung cancer (NSCLC) and renal cell carcinoma.

The detailed response from Bristol-Myers Squibb is given below.

1 Treatment for non-Hodgkin lymphoma

The complainant stated that he/she was visited by the husband of a recently diagnosed patient with non-Hodgkin lymphoma (NHL). Mr X was a member of parliament (MP) and gave the impression that the complainant had not explored all the possible treatments with his wife. Mr X was adamant that a member of the Bristol-Myers Squibb access team had informed him that nivolumab was a good treatment and he was concerned that the complainant was not offering it for his wife.

The complainant understood that nivolumab did not have a licence for NHL. It was available for Hodgkin patients under the early access to medicines scheme (EAMS). This scheme did not mean that the medicine had been declared safe in that its benefits outweighed its side effects, otherwise it would already have a licence and be freely available.

The fact that an MP had been actively informed of this medication even before it had a licence surely showed an issue with how medicines were licensed and how the medical profession were involved and informed.

As a clinician the complainant queried why he/she should be subjected to an MP who was not a health professional questioning his/her professional advice.

The complainant believed that with nivolumab, even for its now licensed indications, MPs were prior to licence, presented with data and medical information and briefed on treatment pathways, etc.

The complainant stated that he/she was informed by the MP that they were regularly 'entertained' by Bristol-Myers Squibb to ensure that if there was ever an issue with formularies that they might step in and influence patient treatment pathways to ensure that a medicine was prescribed.

The complainant stated that he/she was not aware of how MPs influenced prescribing habits, and if they didn't actually have any impact on his/her ability to ensure that patients received the best medication possible, the complainant concluded that Bristol-Myers Squibb was actually promoting a prescription only medicine to members of the public.

This was in itself an insult to the medical profession. It was certainly not appropriate to be approached by a MP who had no specialist knowledge and be exposed to the out of context information that they had received from a pharmaceutical company.

The Panel considered that it was not necessarily unreasonable for pharmaceutical companies to discuss health care and treatments with a variety of audiences including MPs. Companies had to ensure that such activities were in line with the Code including the prohibition of advertising prescription only medicines to the public. The Panel considered that such discussions and activities were more likely to be about the general treatment of a particular disease than the use of a specific medicine for that disease. Companies should be confident that such discussions were only with people whose need for, or interest in, it could reasonably be assumed. The Panel also noted that MPs might be covered by the definition of other relevant decision makers which included those, particularly with an NHS role, who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who were not health professionals. There would inevitably be instances where the provision of appropriate information to MPs might overlap with their own health or that of their friends and families. It was of concern that a health professional had considered that an MP had questioned his/her professional advice based on information allegedly provided by a pharmaceutical company employee. The Code was clear that requests from individual members of the public for advice on personal medical matters had to be refused and the enquirer recommended to consult his or her own doctor or other prescriber or health professional.

The Panel noted Bristol-Myers Squibb's submission that the national policy and access manager for its haemato-oncology role was non-promotional. The job description listed the function as market access with one of the key accountabilities to prepare, champion and execute national policy and access programmes to deliver access in key disease areas. This would surely include use of Bristol-Myers Squibb's products. It was difficult to see how this and other aspects of the role were not within the broad definition of promotion as an activity undertaken by a pharmaceutical company or with its authority which promoted the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines.

In this regard, the Panel noted that the file notes of meetings the Bristol-Myers Squibb national policy and access manager had had with various MPs and the follow-up emails to those MPs included references to specific Bristol-Myers Squibb medicines and to the MPs submitting parliamentary questions to raise issues Bristol-Myers Squibb considered were relevant. There was discussion with at least one MP about what was referred to as the access challenges for cancer medicines in general and Opdivo specifically in renal cell carcinoma. Mention was made of the likelihood of Bristol-Myers Squibb using political support to ensure patients were able to access a different Bristol-Myers Squibb medicine, dasatinib, if a National Institute for Health and Care Excellence (NICE) decision was negative. Reference was made to a roundtable parliamentary discussion in November 2016, which was after the date of the complaint, looking at access to treatments for lymphoma and treatment of Hodgkin lymphoma patients who had failed to respond to or relapsed on other therapies. Mention was made of Bristol-Myers Squibb negotiations with NHS England regarding discounts for dasatinib. Discussions also covered the size of the clinical trial for Bristol-Myers Squibb's medicine for Hodgkin lymphoma; that the clinical trial data was positive and the medicine was suitable for patients who had failed chemotherapy and a stem cell transplant so would not have further treatment options.

The Panel considered that the national policy and access manager's work as shown by the email and file notes promoted specific medicines. Involving politicians and others in activities to increase access to Bristol-Myers Squibb medicines by a Bristol-Myers Squibb employee could not be anything other than promotion. In the Panel's view, certain aspects of the national policy and access manager's role would satisfy that of a representative.

The Panel noted that there were a number of ways that companies could provide information about medicines or indications that were not licensed. Such activity was referred to in the Code, as well as in the PMCPA Guidance on Clause 3. If companies were holding meetings for MPs and other non-health professionals then such meetings should follow the requirements of the Code. The Panel considered that specific decisions on formularies and treatment pathways were for health care providers rather than for individual MPs although of course MPs and local council members might be involved as part of a broader decision making group. Whether such individuals would qualify as other relevant decision makers would depend on their individual circumstances including the role of any decision making group.

Although the Panel had some concerns about the meetings organised/sponsored by Bristol-Myers Squibb in relation to the points outlined above, it noted the information provided by the parties and that there appeared to be a difference of opinion. It noted that the complainant had not provided evidence to support his/her complaint and in the Panel's view had not proved on the balance of probabilities that Bristol-Myers Squibb had promoted its medicine for unlicensed indications to MPs as alleged. It was not clear whether the complainant was concerned about the provision of information to MPs prior to the licensing of Opdivo for any of its indications (according to its summary of product characteristics Opdivo was first authorized in June 2015) or for NHL. The Panel ruled no breaches of the Code including Clause 2.

The Panel did not consider that the complainant had established that Bristol-Myers Squibb's activities with MPs amounted to promotion of prescription-only medicines to the public. Insufficient detail had been provided. Although it was concerned about the detail, it did not consider that the complainant had shown, on the balance of probabilities, that the information was not factual nor presented in a balanced way. The Panel ruled no breaches of the Code.

The Panel noted that the MPs had been provided with limited subsistence at meetings. It did not consider that the complainant had shown, on the balance of probabilities, that gifts, pecuniary advantages or benefits-in-kind had been provided in connection with promotion or as an inducement to recommend any medicine. Nor had the complainant established that MPs had been entertained as alleged. No breaches of the Code were ruled.

2 Meeting in the Republic of Ireland

The complainant stated he/she was even more surprised to hear that in September 2016 Bristol-Myers Squibb had invited a colleague from the UK to a meeting on the use of nivolumab in Hodgkin lymphoma. The meeting was held in the Republic of Ireland. The complainant gave details of the meeting.

The Panel noted that the meeting was held in the Republic of Ireland for health professionals in Eire. There were no UK health professional delegates. The meeting content therefore did not come under the scope of the Code and no breach was ruled in that regard.

As there was a UK health professional speaker the Code applied in relation to the arrangements for him/her. The cost of subsistence, travel and accommodation were not unreasonable in relation to the requirements of the Code and therefore the Panel ruled no breach of the Code.

An anonymous non-contactable complainant submitted a complaint about the conduct of Bristol-Myers Squibb Pharmaceuticals Limited in relation to Opdivo (nivolumab). The complainant stated that he/she was a consultant oncologist and haematologist working in the UK.

Opdivo was licensed for the treatment of certain cancers, these being melanoma, non-small cell lung cancer (NSCLC) and renal cell carcinoma.

COMPLAINT

The complainant was concerned about the behaviour Bristol-Myers Squibb which made nivolumab (Opdivo). The complainant referred to two incidents.

1 Treatment for non-Hodgkin lymphoma

The complainant stated that he/she was visited by the husband of a recently diagnosed patient with non-Hodgkin lymphoma (NHL). Mr X was a member of parliament (MP) and gave the impression that the complainant had not explored all the possible treatments with his wife. Mr X was quite adamant that a member of the Bristol-Myers Squibb access team had informed him that nivolumab was a good treatment and was now available and he was concerned that the complainant was not offering the treatment to his wife.

The complainant's understanding was that nivolumab was already licensed for other indications but did not have a licence for NHL. It was also available for Hodgkin patients under the early access to medicines scheme (EAMS). This scheme did not mean that the medicine had been declared safe in that its benefits outweighed its side effects, otherwise it would already have a licence and be freely available.

The fact that a member of parliament had been actively informed of this medication even before it had a licence surely showed an issue with how medicines were licensed and how the medical profession who actually treated these patients were involved and informed.

As a clinician the complainant queried why he/she should be subjected to a member of parliament who was not a health professional questioning his/her professional advice.

The complainant believed that with nivolumab, even for its now licensed indications, MPs were presented with data and medical information and briefed on treatment pathways, etc, even before the medicine received an official licence from the regulatory authorities.

The complainant stated that he/she was informed by the MP that they were regularly 'entertained' by Bristol-Myers Squibb to ensure that if there was ever an issue with formularies that they might step in and influence patient treatment pathways to ensure that a medicine was prescribed. Whether this actually was a reality or not was beyond the complainant's remit as MPs, unless specialist health professionals in their own right, knew nothing of specialised healthcare medications.

The complainant stated that he/she was not aware of how they influenced prescribing habits, and if they didn't actually have any impact on his/her ability to ensure that his/her patient received the best medication possible, the complainant concluded that Bristol-Myers Squibb was actually promoting a prescription only medicine to members of the public.

This was in itself an insult to the medical profession who spent years studying and specializing to ensure the best possible treatments for patients. It was certainly not appropriate to be approached by an MP who had no specialist knowledge and be exposed to the out of context information that they had received from a pharmaceutical company.

2 Meeting in the Republic of Ireland

The complainant stated he/she was even more surprised to hear that in September 2016 Bristol-Myers Squibb had invited a colleague from the UK to a meeting on the use of nivolumab in Hodgkin lymphoma. The meeting was held in the Republic of Ireland. The complainant provided details of the meeting.

As a general rule the complainant did not see pharmaceutical representatives for these very reasons.

The complainant was concerned that should the press get hold of this – there would be a lot to answer for, from all perspectives and urged the PMCPA to look into the matter.

In writing to Bristol-Myers Squibb the Authority asked it to consider Clauses 2, 3.2, 9.1, 18.1, 22.1, 26.1 and 26.2 of the Code.

RESPONSE

1 Treatment of non-Hodgkin lymphoma (NHL)

Bristol-Myers Squibb submitted that there had been no promotion whatsoever of nivolumab for the investigational disease areas of non-Hodgkin lymphoma or Hodgkin lymphoma and therefore the company rejected the notion that it promoted nivolumab outside the terms of its marketing authorization or in a manner inconsistent with the particulars listed in its summary of product characteristics (SPC). The company denied a breach of Clause 3.2.

Accordingly, it also refuted the alleged breaches of Clauses 9.1, 18.1, 22.1, 26.1, 26.2 and Clause 2 and refuted that there was any pre-licence promotion of nivolumab to health professionals and the public.

Bristol-Myers Squibb submitted that to its knowledge, no Bristol-Myers Squibb employee had ever entered into discussions with any MP about nivolumab for use in NHL nor promoted its use. No Bristol-Myers Squibb employee had discussed the treatment of any MP's spouse or any individual patient.

NHL and Hodgkin lymphoma were distinctly different diseases, although Bristol-Myers Squibb noted there appeared to be some ambiguity between the two in the complaint.

The Bristol-Myers Squibb national policy and access manager for Haemato-Oncology (an entirely non-promotional role) had had discussions with some MPs about Hodgkin lymphoma, solely in relation to disease awareness and forthcoming Health Technology Appraisals (HTAs) of nivolumab in that indication, such as the complexity of forthcoming HTAs in a very small disease population. This would have been within the context of MPs meeting the Code criteria of 'other relevant decision makers'. None of the generic discussions covered detailed medical information, data or treatment pathways.

No materials and/or briefings in relation to NHL were given to the Bristol-Myers Squibb Access Team.

Bristol-Myers Squibb submitted that nivolumab was currently being investigated in NHL and there had been no EU marketing authorisation application.

Nivolumab was not currently available for Hodgkin lymphoma or NHL patients under the Early Access to Medicines Scheme (EAMS).

Bristol-Myers Squibb submitted that it categorically did not provide entertainment and any such provision of entertainment would be a serious breach of Bristol-Myers Squibb's internal policies.

Bristol-Myers Squibb did engage with selected parliamentarians on policy issues of shared interest, particularly in relation to specific diseases, NHS patients' access to medicines and broad healthcare policy. Authorised non-promotional employees might occasionally work with those MPs to hold events with the aim of bringing together other interested parties, supporting disease awareness, stimulating debate and informing policy development.

Occasionally, limited subsistence might be offered during the course of such events; which would be nominal and entirely secondary to the meeting itself.

In the past year, Bristol-Myers Squibb had been involved in organising three such events (two solely and one in partnership), where MPs attended and at which limited subsistence was provided. Such subsistence was only ever provided when the timing and duration of the event warranted it.

The three events were a parliamentary launch of a Bristol-Myers Squibb report on kidney cancer (held in May 2016), a parliamentary launch of a report on multiple myeloma in black communities (held in January 2016) and a round table on rethinking cancer following publication of the international longevity centre (ILC) report commissioned by Bristol-Myers Squibb (held in December 2015). The refreshments provided for these events were similar and mostly included tea, coffee, water and biscuits.

The above information did not include MP-attended events for which Bristol-Myers Squibb was simply an event sponsor. Examples include large conferences co-sponsored by Bristol-Myers Squibb at which a small number of MPs were speakers and patient advocacy group meetings in Parliament that received Bristol-Myers Squibb sponsorship, but in which the company had no further involvement.

The Panel asked Bristol-Myers Squibb's for more information.

Bristol-Myers Squibb stated that as in its original response, the only discussions with MPs in relation to Opdivo and Hodgkin lymphoma were undertaken by its national policy and access manager for haemato-oncology (an entirely non-promotional role). These were solely in relation to disease awareness and forthcoming health technology appraisals (HTAs) of Opdivo in this indication, such as the complexity of forthcoming HTAs in a very small disease population. This was within the context of MPs meeting the Code criteria of 'other relevant decision makers'. None of the generic discussions covered detailed medical information, data or treatment pathways. In no meeting was the treatment of any MP's spouse or any individual patient discussed.

Bristol-Myers Squibb stated that the focus of the anonymous complaint related to its alleged interaction with an MP regarding NHL and it previously confirmed that there were discussions with some MPs regarding Hodgkin lymphoma in the context of disease awareness and forthcoming HTAs. Bristol-Myers Squibb had therefore focused its attention and interpreted the PMCPA's request to provide further details of all meetings and discussions with MPs where Hodgkin lymphoma was discussed. The national policy and access manager for haemato-oncology met with five MPs at which Opdivo and Hodgkin lymphoma was discussed. Details of these meetings were provided including notes of the issues discussed and follow-up emails to the MP for each meeting.

These meetings all took place within the Parliamentary Estate (the MP's workplace), either in general meeting areas or the individual MP's private office. Bristol-Myers Squibb provided no subsistence.

Bristol-Myers Squibb stated that meetings with any individual MP were infrequent and the vast majority would not be repeated within a twelve month period.

MPs were selected by a national policy and access manager on the basis of them having a particular policy responsibility for, or verifiable professional interest in, a relevant issue: in this case the treatment of blood cancer or less-common cancers. Further details were provided.

Bristol-Myers Squibb attendees generally provided no subsistence at such meetings. Where this had occurred in the past, the subsistence would be a tea or coffee purchased from a café in Parliament.

Bristol-Myers Squibb stated that the three meetings took place on the Parliamentary Estate and room rental was not paid for any of these events.

Details of events that were sponsored by Bristol-Myers Squibb in the twelve months prior to 11 October 2016 (the date of the PMCPA's original communication on this case) and where Bristol-Myers Squibb was aware that catering was provided and at least one MP attended, were provided. All of these requests for sponsorship were unsolicited. As event sponsor, Bristol-Myers Squibb had no input into the format, agenda, attendance or catering arrangements for any of these events.

2 Meeting in the Republic of Ireland

Bristol-Myers Squibb submitted that its affiliate in the Republic of Ireland fulfilled a reactive request for a non-promotional haematology medical educational meeting. A leading consultant haematologist based

in the Republic of Ireland, originally requested this educational meeting for haematology health professionals in the local area. The UK speaker was one of the speakers originally identified by the meeting requestor.

All aspects of the meeting were approved internally within Bristol-Myers Squibb to ensure compliance with internal processes, standards and the Irish Pharmaceutical Healthcare Association (IPHA) Code. Additionally, there was also consideration of relevant clauses of the ABPI Code, such as the travel arrangements and hospitality for the UK speaker.

The meeting was held at a named hotel in the Republic of Ireland, with registration commencing at 6.30pm; the meeting started at 7pm and closed at 9pm. A light buffet dinner was provided as subsistence during registration.

The only UK health professional at the meeting was a speaker, a consultant at a hospital. The 30 minute presentation was a highly scientific, balanced overview of 'Relapsed Hodgkin lymphoma (HL) - new developments.' This presentation objectively discussed the Hodgkin lymphoma patient and the slides were examined by Bristol-Myers Squibb to ensure compliance with the IPHA Code.

A scientific advisor from Bristol-Myers Squibb Ireland and nine local health professionals attended (in addition to the two speakers and the original requesting consultant haematologist). The requestor selected the invitees and directed Bristol-Myers Squibb with respect to whom to invite. There were no other UK health professionals present at the meeting. Nor were any Bristol-Myers Squibb sales representatives or Bristol-Myers Squibb staff representing the commercial side of the organisation present at the meeting.

The costs for the light buffet dinner was €27.52 (excluding VAT) per person. Further details on the invitation and breakdown of the subsistence were provided.

Consultancy agreement, honorarium and travelling receipts for the UK speaker were provided.

In summary, Bristol-Myers Squibb submitted that subsistence was strictly limited to the main purpose of the event, was secondary to the purpose of the meeting and focused on appropriate subsistence only.

Whilst the meeting materials were approved in line with the IPHA Code, there was no requirement to examine/certify these materials in line with the ABPI Code as there were no UK delegates at the meeting. The arrangements for the UK speaker were examined as set out in Clause 14.2 of the ABPI Code.

Conclusion

Bristol-Myers Squibb was concerned to hear of the very serious allegations. It did all that it could to comply with the spirit and letter of both the ABPI and IPHA Codes.

As nivolumab was currently only an investigational agent in NHL and Hodgkin lymphoma the company always made comprehensive checks to ensure that any discussions with appropriate health professionals by Bristol-Myers Squibb were strictly in line with the ABPI and IPHA Codes requirements and internal policies.

There had been no promotion of nivolumab for NHL or Hodgkin lymphoma and therefore Bristol-Myers Squibb refuted the allegation of a breach of Clauses 3.2, 18.1, 26.1 and 26.2. The arrangements for meetings also complied with Clause 22.1 with regard to subsistence and venues.

Furthermore as already mentioned, Bristol-Myers Squibb submitted it was diligent in its checks, and conducted itself in a manner which it believed constituted the highest standards, which it expected of itself and in line with expected industry standards and the Code. It therefore failed to see how it could be found to be in breach of Clauses 9.1, or 2.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure stated that anonymous complaints would be accepted, but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. The Panel noted that, in general, extreme dissatisfaction was usually required on the part of an individual before he or she was moved to complain. All complaints were judged on the evidence provided by the parties. The complainant had not provided sufficient information so that the particular circumstances could be identified. The complainant could not be contacted for more information.

1 Treatment for non-Hodgkin lymphoma

The Panel considered that it was not necessarily unreasonable for pharmaceutical companies to discuss health care and treatments with a variety of audiences including MPs. Companies had to ensure that such activities were in line with the Code including the prohibition of advertising prescription only medicines to the public. The Panel considered that such discussions and activities were more likely to be about the general treatment of a particular disease than the use of a specific medicine for that disease. Companies should be confident that such discussions were only with people whose need for, or interest in, it could reasonably be assumed. The Panel also noted that MPs might be covered by the definition in Clause 1.5 for other relevant decision makers which included those, particularly with an NHS role, who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who were not health professionals. There would inevitably be instances where the provision of appropriate information to MPs might overlap with their own health or that of their friends and families. It was of concern that a health professional had considered that an MP had questioned his/her professional advice based on

information allegedly provided by a pharmaceutical company employee. Clause 26.4 of the Code was clear that requests from individual members of the public for advice on personal medical matters had to be refused and the enquirer recommended to consult his or her own doctor or other prescriber or health professional.

The Panel noted Bristol-Myers Squibb submission that the national policy and access manager for haemato-oncology role was non-promotional. The job description listed the function as market access with one of the key accountabilities to prepare, champion and execute national policy and access programmes to deliver access in key disease areas. This would surely include use of Bristol-Myers Squibb's products. It was difficult to see how this and other aspects of the role were not within the broad definition of promotion in Clause 1.2 of the Code as an activity undertaken by a pharmaceutical company or with its authority which promoted the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines.

In this regard, the Panel noted that the file notes of meetings the Bristol-Myers Squibb national policy and access manager had had with various MPs and the follow-up emails to those MPs included references to specific Bristol-Myers Squibb medicines and to the MPs submitting parliamentary questions to raise issues Bristol-Myers Squibb considered were relevant. There was discussion with at least one MP about what was referred to as the access challenges for cancer medicines in general and Opdivo specifically in renal cell carcinoma. Mention was made of the likelihood of Bristol-Myers Squibb using political support to ensure patients were able to access dasatinib if a National Institute for Health and Care Excellence (NICE) decision was negative. Reference was made to a roundtable parliamentary discussion in November 2016 looking at access to treatments for lymphoma and treatment of Hodgkin lymphoma patients who had failed to respond to or relapsed on other therapies. Mention was made of Bristol-Myers Squibb negotiations with NHS England regarding the provision of dasatinib at a discounted price. Discussions also covered the size of the clinical trial for Bristol-Myers Squibb's medicine for Hodgkin lymphoma; that the clinical trial data was positive and the medicine was suitable for patients who had failed chemotherapy and a stem cell transplant so would not have further treatment options.

The parliamentary event regarding Hodgkin lymphoma was planned for 29 November. The Panel noted that this was after the date of the complaint (1 October 2016).

The Panel was concerned that it was only when Bristol-Myers Squibb was asked for additional information that the detailed information about the meetings with MPs was supplied.

The Panel considered that the national policy and access manager's work as shown by the email and file notes promoted specific medicines. Involving politicians and others in activities to increase access to Bristol-Myers Squibb medicines by a Bristol-Myers Squibb employee could not be anything other than promotion. In the Panel's view, certain aspects of the national policy and access manager's role would satisfy that of a representative as defined in Clause 1.7.

The Panel noted that there were a number of ways that companies could provide information about medicines or indications that were not licensed. Such activity was referred to in the Code, including Clause 3 as well as in the PMCPA Guidance on Clause 3. If companies were holding meetings for MPs and other non-health professionals then such meetings should follow the requirements of Clause 22 in relation to the arrangements. The Panel considered that specific decisions on formularies and treatment pathways were for health care providers rather than for individual MPs although of course MPs and local council members might be involved as part of a broader decision making group. Whether such individuals would qualify as other relevant decision makers would depend on their individual circumstances including the role of any decision making group.

In the Panel's view there was little evidence to link the company's activities with MPs to the situation the complainant had raised. The complainant had not provided sufficient information so that the particular circumstances could be identified and he/she could not be contacted for more information.

Although the Panel had some concerns about the meetings organised/sponsored by Bristol-Myers Squibb in relation to the points outlined above, it noted the information provided by the parties and that there appeared to be a difference of opinion. It noted that the complainant had not provided evidence to support his/her complaint and in the Panel's view had not proved on the balance of probabilities that Bristol-Myers Squibb had promoted its medicine for unlicensed indications to MPs as alleged. It was not clear whether the complainant was concerned about the provision of information to MPs prior to the licensing of Opdivo for any of its indications (according to its summary of product characteristics Opdivo was first authorized in June 2015) or for NHL. Bristol-Myers Squibb had been asked to respond in relation to Clause 3.2 not Clause 3.1. The Panel ruled no breach of Clause 3.2 of the Code. It also ruled no breach of Clauses 9.1 and 2.

The Panel did not consider that the complainant had established that Bristol-Myers Squibb's activities with MPs amounted to promotion of prescription-only medicines to the public. Insufficient detail had been provided. No breach of Clause 26.1 was ruled. Although concerned about the detail, the Panel did not consider that the complainant had shown, on the balance of probabilities, that the information was not factual nor presented in a balanced way. The Panel ruled no breach of Clause 26.2.

The Panel noted that the MPs had been provided with limited subsistence at meetings held by Bristol-Myers Squibb or sponsored by Bristol-Myers Squibb. It did not consider that the complainant had shown, on the balance of probabilities, that

gifts, pecuniary advantages or benefits-in-kind had been provided in connection with promotion or as an inducement to recommend any medicine. No breach of Clause 18.1 was ruled. Nor had the complainant established that MPs had been entertained as alleged. No breach of Clause 22.1 was ruled.

2 Meeting in the Republic of Ireland

The Panel noted that the meeting was held in the Republic of Ireland for health professionals in Eire. There were no UK health professional delegates. The meeting content therefore did not come under the scope of the ABPI Code and no breach was ruled in that regard.

The ABPI Code applied in relation to the arrangements for the UK health professional speaker. It did not appear that the arrangements for the UK speaker were unreasonable. The cost of subsistence, travel and accommodation were not unreasonable in relation to the requirements of Clause 22.1. The Panel therefore ruled no breach of Clause 22.1.

Complaint received **11 October 2016**

Case completed **19 January 2017**