ANONYMOUS, NON CONTACTABLE v BRISTOL-MYERS SQUIBB

Promotion of Daklinza

An anonymous, non-contactable complainant complained about the promotion of Daklinza (daclatasvir dihydrochloride) by Bristol-Myers Squibb Pharmaceuticals at a conference in June 2016. Daklinza was indicated in combination with other medicinal products for the treatment of chronic hepatitis C virus (HCV) infection in adults.

The complainant explained that the event covered all aspects of care including not only clinicians but also non-clinical and non-NHS delegates from many parts of the care community including the public providing volunteer care work.

The complainant attended a presentation in the keynote lecture theatre on day 1 that was open to all delegates including non-medical attendees and the public. A promotional piece for Daklinza, a prescription only medicine was put on every seat in the room. The complainant stated that such behaviour brought the industry into discredit as the meeting room was for education and not promotion. The complainant alleged that a prescription only medicine had been promoted to the public. This was a very serious breach.

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

The Panel noted that the Code applied to the promotion of medicines to members of the United Kingdom health professions and to other relevant decision makers. 'Other relevant decision makers' was defined as particularly those 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.

The Panel noted that the conference was a specialist meeting not aimed at the public. It was described as an integrated care conference that enabled health and social care professionals to forge new partnerships and productive ways of working. It brought the NHS and local authorities together and represented the largest annual gathering of commissioners, providers and their suppliers. Delegates were described as senior managers or higher although this was not necessarily clear from examination of the delegate list. It was made up of four events and was described as a trade-only event targeting health professionals and more specifically NHS payors and commissioners. The Panel noted that the show also targeted those involved in home and residential care. The marketing to potential delegates was stated to be via professional trade publications and websites. Consumers and direct patients were refused entry.

The leavepiece at issue was put on the seats for the attendees of five non sponsored sessions. The sessions were identified in advance and agreed verbally between Bristol-Myers Squibb and the organisers where it was considered that stakeholders would find the information regarding the National Institute for Health and Clinical Excellence (NICE) approval relevant.

The Panel noted that the complainant was concerned about the distribution of the leavepiece at a presentation on day 1 in the keynote lecture theatre. The presentation was not identified by the complainant. The Panel noted that the leavepiece was circulated at three presentations on that day, one in the keynote debate theatre 'Integrated care, what does it actually mean?' and the others in the Future of Clinical Commissioning Theatre and Medicines Optimisation Congress. The Panel noted the status of the audience on day 1 as set out in the delegate list. Although the Panel queried some of those listed, the majority were either health professionals or had a professional interest in healthcare such that, on the balance of probabilities, they appeared to meet the definition of other relevant decision makers. The nature of the identified sessions on day 1 would be clearly aimed at health professionals and/or other relevant decision makers. The Panel noted that the complainant had to establish that the attendees of the presentation that he/she referred to were other than health professionals and other relevant decision makers. The complainant had submitted no evidence in this regard. The Panel did not consider that providing the leavepiece to the attendees at the sessions on day 1 constituted advertising a prescription only medicine to the public as alleged. The Panel therefore ruled no breach of the Code.

The Panel was concerned that the relevant sessions for distribution of the material were agreed verbally; there were no written details about the arrangement or confirmation of any compliance assessment. Nonetheless, given its ruling of no breach, the Panel did not consider that Bristol-Myers Squibb had failed to maintain high standards nor had it brought discredit upon the pharmaceutical industry and ruled no breach of the Code including Clause 2.

An anonymous, non-contactable complainant complained about the promotion of Daklinza (daclatasvir dihydrochloride) by Bristol-Myers Squibb Pharmaceuticals Limited at a 2-day conference in June 2016.

Daklinza was indicated in combination with other medicinal products for the treatment of chronic hepatitis C virus (HCV) infection in adults.

COMPLAINT

The complainant explained that the event which he/she attended both days covered all aspects of care including not only clinicians but also non-clinical

and non-NHS delegates from many parts of the care community including the public providing volunteer care work.

The complainant explained the format was a large exhibition hall with a variety of lecture theatres strategically located to provide health education in different formats. These educational sessions were non promotional.

The complainant attended a presentation in the keynote lecture theatre on day 1 that was open to all delegates including non-medical attendees and the public. Bristol Myers Squibb representatives deposited a promotional piece for Daklinza which was a prescription only medicine on every seat in the room.

The complainant stated that such behaviour brought the industry into discredit as the meeting room was for education and not promotion. The complainant alleged that not all of the delegates attending lectures were medical and therefore a prescription only medicine had been promoted to the public. The complainant stated that it was clear that all promotion should take place away from the delivery of education and that promotion to the public was not permitted under the Code and as a result it was a very serious breach.

When writing to Bristol-Myers Squibb the Authority asked it to respond to Clauses 2, 9.1 and 26.1 of the Code.

RESPONSE

Bristol-Myers Squibb disputed the notion that it promoted to members of the public and denied a breach of Clause 26.1 and also refuted the alleged breaches of Clauses 9.1 and 2.

Bristol-Myers Squibb submitted that the event referred to by the complainant was the largest national integrated care conference in the UK, with nearly 9000 attendees and over 350 sponsors/ exhibitors present. Promotion of the event by the organisers was limited to communication channels targeted at health professionals and other relevant decision makers as follows:

- BMJ
- Guidelines in Practice (a primary care journal that contained numerous advertisements for prescription medicines)
- Doctors.net (an online platform exclusively for doctors)
- Primary Care Today
- National Association of Primary Care
- NHS Clinical Commissioners
- Practice Index.

Bristol-Myers Squibb stated that its sponsorship included stand space and a symposium slot. However, after the contract was entered into, Bristol-Myers Squibb decided not to progress with the symposium due to company prioritisation, and instead was offered the opportunity to have the leavepiece distributed to the presentations mentioned below.

Bristol-Myers Squibb sponsored this event with the strategic objective to continue to maintain engagement directly with healthcare policy makers and budget holders. Prior to committing to sponsoring the event, Bristol-Myers Squibb referred to the guidance on the organisers' website, and verbal communication between the Virology Access and Partnership lead with the organisers. It was this information, upon which the company relied in order to make an informed judgement that the conference was indeed targeted at NHS commissioners, health professionals and other relevant decision makers. This was recently re-confirmed by the organisers.

As detailed above, the intended audience for the conference was health professionals and other relevant decision makers. The delegate lists provided by the organisers upon request for each session confirmed that. There were several other pharmaceutical companies that also exhibited at this conference. A list was provided. Attendance attracted twelve self-accredited CPD points.

Daklinza was a prescription only treatment regimen for chronic hepatitis C (HCV), more specifically Genotype 3 (GT 3) patients. The National Institute for Health and Care Excellence (NICE) recently granted approval for Daklinza in November 2015, and the decision was implemented in February 2016. This was significant news for NHS budget holders, as HCV treatment would have a considerable impact on their budgets which would be funded centrally by NHS England rather than local budgets. In this context, it was customary for Bristol-Myers Squibb to appropriately communicate the recent NICE approval to health professionals and other relevant decision makers.

The Daklinza leavepiece was certified for promotional use in February 2016. It was a 4-sided flyer that focused on the recent NICE approval (in the public domain via the NICE website) with the appropriate associated clinical information:

- Page 1 clearly stated the fact of the NICE approval.
- Page 2 showed the NICE guidance for each patient type in a tabulated form.
- Page 3 contained three simple messages indicating the key features of the product to understand the context of the NICE guidance.
- Page 4 was the prescribing information.

In that context, Bristol-Myers Squibb submitted that the leavepiece was appropriate for prescribers and other relevant decision makers.

Bristol-Myers Squibb recognised that the specific presentations might not be directly associated with hepatitis C, however, all attendees were expected to be health professionals and other relevant decision makers, who typically had multiple therapy area responsibilities.

Six Bristol-Myers Squibb employees attended the conference and details were provided.

1200 copies of the leavepiece were delivered to the conference organisers, and as instructed verbally by the Bristol-Myers Squibb Virology

Access and Partnership team. The leavepiece was distributed by organisers onto seats in five lecture theatres, as follows:

- Keynote debate theatre at noon on day 1 – Integrated care, what does it actually mean
- Keynote debate theatre at noon on day 2 – Reshaping hospital care for the 21st century: moving from institutions to networks and chains
- Future of clinical Commissioning at noon on day 1 – Commissioning for improved mental health
- Future of clinical Commissioning at noon on day 2 – Countdown to accountable care in East Sussex
- Medicines Optimisation theatre at noon on day 1 – Pharmacy in care homes, a model for implementation and system change.

The audience for each of these sessions consisted of health professionals and other relevant decision makers. In collaboration with the organisers, Bristol-Myers Squibb selected sessions where the two jointly believed stakeholders would find the information contained in the leavepiece regarding NICE approval relevant.

Bristol-Myers Squibb submitted that it was extremely concerned to hear of the very serious allegations which had been levied against it. Bristol-Myers Squibb was a company that did all that it could to comply with the spirit and letter of the Code. Bristol-Myers Squibb submitted that it made comprehensive checks to ensure that the audience at the conference and in particular the presentations at which the leavepiece was distributed consisted of health professionals and other relevant decision makers, and it was given the assurances it was looking for. Bristol-Myers Squibb therefore refuted the allegation of a breach of Clause 26.1.

Further, Bristol-Myers Squibb submitted that it was diligent in its checks, and conducted itself in a manner which constituted the highest standards, which it expected of itself and in line with expected industry standards and the Code. Bristol-Myers Squibb 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 Clause 1.1 stated that the Code applied to the promotion of medicines to members of the United Kingdom health professions and to other relevant decision makers.

'Other relevant decision makers' was defined in Clause 1.5 as particularly those 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.

The Panel noted that the conference was a specialist meeting not aimed at the public. It was described as an integrated care conference that enabled health and social care professionals to forge new partnerships and productive ways of working. It was the only show to bring NHS and local authorities together and represented the largest annual gathering of commissioners, providers and their suppliers. Every delegate was described as a senior manager or higher although this was not necessarily clear from examination of the delegate list. It was made up of four events; details were provided. It was described by the media agency which organised the event as a trade only event targeting health professionals and more specifically NHS payors and commissioners. The Panel noted that the show also targeted those involved in home and residential care. The marketing to potential delegates was stated to be via professional trade publications and websites. Consumers and direct patients were refused entry.

The leavepiece at issue was put on the seats for the attendees of five non sponsored sessions. The sessions were identified in advance and agreed verbally between Bristol-Myers Squibb and the organisers where it was considered that stakeholders would find the information regarding NICE approval relevant.

The Panel noted that the complainant was concerned about the distribution of the leavepiece at a presentation on day 1 in the keynote lecture theatre. The presentation was not identified by the complainant. The Panel noted that the leavepiece was circulated at three presentations on 29 June one in the keynote debate theatre 'Integrated care, what does it actually mean?' and the others in the Future of Clinical Commissioning Theatre and Medicines Optimisation Congress. The Panel noted the status of the audience on day 1 as set out in the delegate list. Although the Panel queried some of those listed, the majority were either health professionals or had a professional interest in healthcare such that, on the balance of probabilities, they appeared to meet the definition of other relevant decision makers as set out in Clause 1.5. The nature of the identified sessions on day 1 would be clearly aimed at health professionals and/or other relevant decision makers. The Panel noted that the complainant, who was anonymous and non-contactable, bore the burden of proof and thus had to establish that the attendees of the presentation that he/she referred to were other than health professionals and other relevant decision makers. The complainant had submitted no evidence in this regard. The Panel did not consider that providing the leavepiece to the attendees at the sessions on day 1 constituted advertising a prescription only medicine to the public as alleged. The Panel therefore ruled no breach of Clause 26.1.

The Panel was concerned that the relevant sessions for distribution of the material were agreed verbally; there were no written details about the arrangement or confirmation of any compliance assessment. Nonetheless, given its ruling of no breach of Clause 26.1, the Panel did not consider that Bristol-Myers Squibb had failed to maintain high standards nor had it brought discredit upon the pharmaceutical industry. Thus the Panel ruled no breach of Clauses 9.1 and 2.

Complaint received **29 July 2016**

Case completed **2 September 2016**