CASE AUTH/3335/4/20

EX-PHARMACEUTICAL COMPANY EMPLOYEE v BRITANNIA

Advisory Board meetings

An ex-employee of Britannia alleged that advisory boards about Apo-Go (apomorphine hydrochloride), used in the treatment of patients with Parkinson's disease, organized by the company over the previous two years were promotional. The complainant stated that the advisory boards were organized by marketing and sales; attendees were selected based on the criteria put together by marketing and sales. There was no medical representation at the meetings; a medical employee at the time refused to attend as he/she considered that the meetings were promotional. The complainant queried what advice would be required for a product that had been on the market for more than 20 years.

The complainant alleged that the outputs of the advisory boards were often shared with sales and marketing staff even before the participants received formal notes. There was no instruction on how the outputs would be used and they had a promotional look.

Given the pressure from the marketing and sales team, the complainant stated that he/she was not surprised that the senior medical employee and compliance employee approved the meetings.

The complainant alleged that the culture of non-compliance within the company came from the top. The complainant stated that he/she was only now able to complain because otherwise he/she had previously feared dismissal if he/she had shared concerns with senior managers.

The detailed response from Britannia is given below.

The Panel noted that it was acceptable for companies to pay health professionals and others for relevant advice. Nonetheless, the arrangements for such meetings had to comply with the Code. To be considered a legitimate advisory board the choice and number of participants should stand up to independent scrutiny; each should be chosen according to their expertise such that they would be able to contribute meaningfully to the purpose and expected outcomes of the advisory board. The number of participants should be limited so as to allow active participation by all. The agenda should allow adequate time for discussion. The number of meetings and the number of participants should be driven by need and not the invitees' willingness to attend. Invitations to participate should state the purpose of the advisory board meeting, the expected advisory role and the amount of work to be undertaken. If an honorarium was offered, it should be made clear that it was a payment for such work and advice. Honoraria must be reasonable and reflect the fair market value of the time and effort involved.

The Panel noted the submission from Britannia as to the reasons for the six advisory boards and considered the arrangements for each advisory board in detail.

It appeared that there had been a lot of activity following the publication of the TOLEDO study. This was not, in itself, necessarily unacceptable under the Code but the Panel had concerns about the overall impression given by the advisory boards.

The Panel was concerned that for some meetings the proportion of time on the agenda allocated to presentations did not appear to allow adequate time for discussion. Feedback from the participants should be the main focus of advisory boards and only a small proportion of the time should be spent on company presentations. In this regard, the Panel noted that SOP CO40V01 Advisory Boards, effective 22 February 2019 clarified that the proportion of discussion time compared with presentation time should usually be 70% and 30% respectively and queried whether this was sufficient.

The Panel noted Britannia's submission that, in some situations, advisors were proposed jointly between the medical and marketing teams using their combined knowledge from working for many years in the therapy area.

The Panel further noted Britannia's submission that a senior medical employee had attended two of the six advisory boards and certified the meeting approval form (MAF) and materials for all meetings and would clearly not have done so if he/she considered that the meetings were promotional. According to Britannia, the signatories operated autonomously and were freely able to insist on changes being made when needed to ensure the meetings were run in a compliant manner.

The Panel noted Britannia's submission that the minutes, when written, where the views of specific advisors were documented, were not shared with sales staff but the advice solicited was clearly used to formulate strategic plans and marketing plans for the business and hence must be shared within the marketing/medical team.

The Panel was also concerned regarding the number of advisors and the ratio of Britannia staff to advisors at some meetings, the lack of pre-reading for some of the meetings given their purpose, the lack of chair and staff briefing and that minutes were not always prepared. It appeared that preparation time was paid when there was no pre-reading (25, 26 January 2019 advisory board).

Given all these concerns, the Panel considered that Britannia had failed to maintain high standards in relation to the advisory boards in general and a breach of the Code was ruled.

Although the Panel had concerns, noted above, and ruled a breach of the Code, it did not consider that these concerns also warranted a ruling of a further breach of the Code. It also noted that the complainant had provided limited evidence to show, on the balance of probabilities, that the arrangements were unacceptable as alleged. The Panel therefore ruled no breaches of the Code (one of these rulings was appealed by the complainant).

The Panel did not consider that the complainant had provided evidence to show that the senior medical and compliance employees were pressured into approving the meetings

or that there was a culture of non-compliance within the company as alleged. The Panel therefore ruled no breach of the Code.

On balance, the Panel did not consider that the complainant had provided evidence to show that the circumstances warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure. This ruling was appealed by the complainant.

The Appeal Board was concerned about Britannia's deviation from its SOPs for advisory boards including (i) that commercial staff were present as observers without any clearly defined role and (ii) that the maximum number of advisors was exceeded on a number of occasions without proper recording or investigation of that deviation. The Appeal Board noted that whilst the involvement of and attendance at advisory boards by commercial staff was not necessarily unacceptable, the external perception of such was important.

The Appeal Board was very concerned that Britannia had not provided all the documents to the Panel: certain materials were only provided for the appeal. In that regard the Appeal Board noted that in response to the complainant's appeal, Britannia had provided an internal summary booklet for the advisory boards held on the 24/25 January 2020, 8/9 February 2020 and 28/29 February 2020. The Appeal Board was concerned that this was a summary only, queried why it was not provided to the Panel and considered that no satisfactory explanation was given. The Appeal Board was concerned about a lack of detailed minutes for the advisory boards and that in some instances there were no minutes at all. The Appeal Board noted that the Code required the company to maintain records concerning the services provided by consultants. The Appeal Board queried how, without such record keeping, appropriate use was made of the advisors' input in the advisory board meetings at issue.

The Appeal Board noted slides from Britannia's 2020 Brand Plan and had concerns around the use of commercial terminology when discussing advisory boards. For example, Evoke was listed as a Strategic Objective (key performance indicator (KPI)) under 'What? Tactic description' with the 'How? Tactic description' described as '2-3 ad boards per year for intl. KOLs, rising stars & nurses'.

The Appeal Board noted its comments and concerns above and considered that the arrangements for the advisory boards at issue were such that the requirements under the Code were not met and it thus ruled a breach of the Code. The complainant's appeal on this point was successful.

Despite its concerns the Appeal Board considered that it had not been established, on the balance of probabilities, that the Britannia advisory boards at issue did not include legitimate content or that legitimate business questions were not being addressed.

Although concerned about the arrangements for the advisory boards, the Appeal Board did not consider that the circumstances in this case amounted to a breach of Clause 2 which was a sign of particular censure and was reserved for such use and it upheld the Panel's ruling of no breach of Clause 2. The appeal on this point was unsuccessful.

An ex-employee of Britannia alleged that advisory boards organized by the company over the previous two years were promotional, although he/she suspected the issue went back much further.

The advisory boards appeared to be about Apo-Go (apomorphine hydrochloride), used in the treatment of patients with Parkinson's disease.

COMPLAINT

The complainant stated that the advisory boards were organized by marketing and sales; there was no medical representation at the meetings. A senior medical employee refused to attend as he/she considered that the meetings were promotional.

The complainant stated that attendees were selected based on the criteria put together by marketing and sales. The content was promotional. The complainant queried what advice would be required for a product that had been on the market for more than 20 years.

The outputs of the advisory boards were often shared with sales and marketing staff even before the participants received formal notes (the complainant did not know if formal notes were ever sent to participants). There was no instruction on how the outputs would be used (sales team). The outputs sent by marketing had a promotional look.

Given the pressure from the marketing and sales team, the complainant stated that he/she was not surprised that the senior medical and compliance employees and approved the meetings.

The complainant alleged that the culture of non-compliance within the company came from the top, the Britannia Management Committee. The complainant alleged that the company was run like a dictatorship and there was no interest in compliance; anyone who challenged was sacked. The complainant stated that he/she was only now able to complain because otherwise he/she had previously feared dismissal if he/she had shared concerns with senior managers.

When writing to Britannia, the Authority asked it to consider the requirements of Clauses 2, 9.1, 18.1 and 23.1 of the Code.

RESPONSE

Britannia noted the complainant's query as to why the company needed to seek any advice for a product when it had been on the market for 20 years. In that regard, Britannia noted that the APO-go brand consisted of three products:

- APO-go Pen 10mg/ml Solution for Injection – first registered March 1999
- APO-go AMPOULES 10mg/ml Solution for Injection or Infusion – first registered January 2000
- APO-go PFS 5mg/ml Solution for Infusion in Pre-filled Syringe – first registered September 2004.

Britannia explained that when the products were registered, the standards for clinical trial evidence were different to those expected today. As a result, Britannia struggled to obtain recommendations for APO-go in international and national guidelines due to the lack of level 1 (randomised, placebo-controlled trial) data. Britannia therefore sponsored such a trial, the TOLEDO study, and the clinical study report (CSR) was approved in October 2018. The availability of this trial was fundamental to two regulatory submissions: a decentralised EU application for a new product in the APO-Go range (APO-go POD cartridge for infusion) and an application for APO-go infusion in the US via Britannia's

US commercialisation partner US WorldMeds (USWM). Each of these submissions also necessitated a change in the ancillary medical devices used to administer the medicine by infusion which would make it easier for Parkinson's patients to use Apo-Go in a self-care environment.

Britannia stated that it was against this background that the advisory panels, which ran between January 2019 and February 2020, were planned and executed. The EU application was submitted in December 2018 and the US application was planned for 2020. Hence, despite the complainant's assertion that no advice could be needed, there were, at the time, very important strategic launch planning activities that required Britannia to solicit the advice of appropriately selected UK and international advisors. Since Parkinson's disease was managed by movement disorder specialists in some locations, neurologists in other locations and required nursing support in the home to set up and manage the infusions, a range of advisors were needed.

Britannia asserted that there was no breach of Clause 23 (legitimate need for services) and that, overall, the rationale for holding advisory boards was sound and did not breach Clauses 2, 9.1 or 18.1.

Britannia stated that experts in Parkinson's disease were not as common as, for example, experts in managing hypertension. The management of Parkinson's patients necessitated effective working relationships between tertiary referral centres where such patients were referred for specialist care by movement disorder specialists, neurologists who looked after these patients once care had been established and nurses who cared for them at home. Working for many years in the therapy area, Britannia's medical and marketing team members had become aware of the relevant key opinion leaders and experts who were working actively in their countries. Through attendance at learned society meetings, and appraisal of emerging research evidence, Britannia medical and marketing staff maintained awareness of the interests of experts working in the field and specifically those with expertise in device-aided medicinal and surgical therapies. Britannia partnered with other companies in different countries to distribute apomorphine. In some situations, advisors were proposed jointly between the medical and marketing teams of the relevant companies. Advisors for each advisory board were therefore selected to receive invitations to participate in advisory meetings using this combined knowledge. Since Britannia was a small company whose business activities were almost entirely focused on Parkinson's disease, the process of selecting advisors was straightforward. Britannia asserted that there was no breach of Clause 23 (advisors must be selected by someone with expertise necessary to evaluate their ability to provide the advice required).

Britannia stated that there had been 6 advisory boards held between January 2019 and February 2020, the timeframe within the scope of this complaint and provided details including the date the meeting approval form was signed.
Britannia noted that four standard operating procedures (SOPs) were in place when the meetings were held:

1 CO15V01 Meetings and Hospitality, effective date 28 April 2017 – applicable to advisory boards held on 9 January and 25/26 January 2019.

Summary of key points:

- Covered the requirements for choice of venues, provision of subsistence.
- The requirement for agendas and slides to be certified.

- Reiterated the requirements of CO16 in relation to engaging consultants, contracts and payments/disclosures.

2 CO16V01 Engaging Consultants, effective 28 April 2017 (and associated Work Instructions Fair Market Value Guidance CO16WI01 V01 effective 28 April 2017) – applicable to advisory boards held on 9 January and 25/26 January 2019.

Summary of key points:

- Specified the requirement to have a defined purpose for engaging a consultant and that the person engaged must have the appropriate experience to perform the activity.
- That transfers of value must be in keeping with company guidelines and disclosed (as per the Work Instructions on Fair Market Value).
- That signed agreements between the consultant and the company were required prior to performing the services or receiving payment for the services.
- That the number of consultants engaged should not be greater than the number needed to achieve the identified aim.
- That the procedure applied to activities organised by Britannia UK, regardless of the country where the activity occurred or the nationality of the consultant.
- Provided specific guidance as to the extent and nature of any expenses, travel and accommodation that would be provided and/or paid for.

3 CO40V01 Advisory Boards, effective 22 February 2019 (applicable to Advisory Boards run in September 2019 and all advisory boards in 2020).

Britannia stated that this new SOP was introduced to better control the process of advisory boards, which had previously been covered under the more general Meetings and Hospitality SOP CO15.

Summary of key points:

- Introduced the requirement that the MAF must be certified prior to any meeting arrangements, logistics or invitations being actioned.
- Specified the requirements that an advisory board should be for appropriate business needs to gather advice and insight and not to promote or influence prescribing or solely to share information.
- It recommended no more than 10 advisors per meeting, while recognising the number needed might vary depending on the nature of advice sought and international variation in practice.
- Clarified that the proportion of discussion time compared with presentation time should usually be 70% and 30% respectively.
- That internal attendees should have a specific role at the meeting.

4 CO16V02 Engaging a Health Professional as a Consultant, effective 4 March 2019 (in association with Work Instructions Fair Market Guidance CO16WI01 V03 effective 26 July 2019) – applicable to Advisory Boards held in September 2019 and all boards in 2020.

The main changes in this SOP were to align with a new company procurement policy. Otherwise, the main points were as above re CO16V01.

Britannia submitted that, in summary, SOPs were in place covering the use of health professionals as consultants, arrangements for meetings and hospitality as well as, latterly, specific guidelines for advisory boards.

Britannia provided comprehensive details of each advisory board including the number of advisors at each meeting, whether attendees were paid, Britannia staff attendees (their job title and role at the meeting), summary of the advice sought, whether there was a *bona fide* need for the advice, how the advice was used plus supporting evidence by way of agendas, invitations, certificates, presentations etc.

Meeting Approval Forms (MAFs)

Britannia submitted that meeting approval forms MAFs were completed to outline the purpose of the meeting and all attendant arrangements. When meetings were organised under CO15 Meetings and Hospitality there was no requirement to have the MAF certified before arrangements were started, so that invitations and agendas could be prepared before the MAF received final certification (eg due to the need to wait for confirmation of dates from invited advisors to book a venue).

Once the CO40 Advisory Boards SOP was introduced in February 2019, an initial MAF had to be certified before any arrangements could be made. As the arrangements for a meeting crystallised, eg the date that was most convenient for invited advisors, an appropriate location etc, the MAF might be updated and recertified during the planning process.

All the advisory boards had certified MAFs before the meetings were held in accordance with the SOP in place at the time.

Agendas

Britannia stated that for some meetings, a separate agenda was prepared and certified. However, in many cases this was superseded by an agenda certified within the approved slides to be used at the advisory board. Meetings held under CO40 paid strict attention in the crafting of the agenda to the need for there to be at least 70% of the time devoted to discussion vs presentation time.

The agendas for all meetings were certified in accordance with the SOP in place at the time, whether separately or incorporated into meeting slides.

Slides

Britannia stated that the slides were all certified in advance of the meeting in accordance with the SOP in place at the time.

Briefing documents/feedback forms

Britannia submitted that any briefing of invited advisors acting as moderators or facilitators was done either on site before the meeting started or by telephone. In many cases, the expertise of the moderators/facilitators in chairing meetings meant that no specific briefing was required. It was not Britannia's practice to ask for delegate feedback forms from advisory boards.

Only very small numbers of Britannia staff were involved in advisory boards and briefing documents had not been deemed necessary.

Britannia submitted that the complainant's assertion that a medical employee had refused to attend advisory board meetings, because he/she considered that they were promotional, was not true. The medical employee had attended two of the six advisory boards and certified the MAF and materials for all meetings and would clearly not have done so if he/she considered that the meetings were promotional. The medical employee did not attend the other four meetings and details were provided

Verbatim minutes (when written), where the views of specific advisors were documented, were not shared with sales staff but were circulated internally within the marketing team. In addition, the advice solicited from advisory boards was clearly used to formulate strategic plans and marketing plans for the business and hence must be shared within the marketing/medical team. There would be no purpose in soliciting the advice of experts if said advice was not used within the business.

Regarding pressure placed on signatories by sales and marketing teams, there was no possibility of pressure being placed on signatories by sales as no-one from sales organised any advisory boards. There could be, on occasion, time pressures and disagreements between organisers and signatories regarding content that an external observer might perceive as pressure. However, when all the advisory boards at issue were held, the signatories operated autonomously and were freely able to insist on changes being made when needed to ensure the meetings were run in a compliant manner.

In summary, Britannia asserted that, in the organisation of advisory boards, there had been no breaches of Clauses 2, 9.1, 18.1 or 23.

PANEL RULING

The Panel noted that the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant had provided no evidence to support his/her allegations. The PMCPA was not an investigatory body as such.

The Panel noted that it was acceptable for companies to pay health professionals and others for relevant advice. Nonetheless, the arrangements for such meetings had to comply with the Code, particularly Clause 23. To be considered a legitimate advisory board the choice and number of participants should stand up to independent scrutiny; each should be chosen according to their expertise such that they would be able to contribute meaningfully to the purpose and expected outcomes of the advisory board. The number of participants should be limited so as to allow active participation by all. The agenda should allow adequate time for discussion. The number of meetings and the number of participants should be driven by need and not the invitees' willingness to attend. Invitations to participate should state the purpose of the advisory board meeting, the expected advisory role and the amount of work to be undertaken. If an honorarium was offered, it should be made clear that it was a payment for such work and advice. Honoraria must be reasonable and reflect the fair market value of the time and effort involved.

The Panel noted the submission from Britannia as to the reasons for the advisory boards. The Panel then went on to consider the arrangements for each advisory board as follows.

The Panel noted that according to the MAF for the TOLEDO Secondary Data Advisory Board held on 9 January 2019 in Frankfurt, the objective of the advisory board was to 'share the full open label data set with selected health professionals and receive feedback on three questions. The questions included the possible practical use of the data and protocol. The attendees were the TOLEDO European investigators. According to Britannia, 4 members of staff attended this advisory board. The advisory board lasted four hours starting at 9.30; the first hour was for arrivals and coffee. Between 10.30 and 12.30, there was a review of the open label data reported in the final CSR and a review of the *post-hoc* analysis of the data which was requested by the advisors in June 2018 following discussion of the initial OLP data and was presented by a Britannia employee and one of the attendees. Questions were included within this two hour period; there was no breakdown of the time spent on presentation versus discussion. Lunch was available from 12.30-13.30. Whilst there was no mention in the initial invitation, the MAF referred to delegates being paid for doing 5 hours preparation including reading of the CSR (167 pages) and reviewing additional analysis and two hours at the meeting. According to the minutes of the meeting the materials to be circulated for pre-reading included the final TOLEDO CSR and the complete slide deck summarising TOLEDO OLP data, as reported in the final CSR, and requested *post-hoc* analyses on pooled data. The Panel therefore queried why 64 slides on the key TOLEDO Study OLP safety and efficacy data as reported in the final CSR were presented at the meeting and queried whether there would be sufficient time for the attendees to give feedback. Further, it appeared that all but one of the 8 advisors who attended the advisory board were cited as authors on the publication of what was described in the minutes as the full primary publication of the DBP data in The Lancet Neurology, September 2018. It was unclear to the Panel why the attendees (who were described on the MAF as the TOLEDO European investigators) would need so much time paid to read the TOLEDO CSR and read and listen to the presentation. The Panel noted that the invitation to the advisory board meeting described it as the TOLEDO Investigators Advisory Board and stated that it would be followed by a non-paid secondary publications meeting (13.30-16.00) to define potential publications for the TOLEDO long-term follow-up data. The attendees of the advisory board were all invited to the publications meeting. According to the agenda for the publications meeting, attendees would review the morning's findings relevant to publications. It was unclear to the Panel why the review of the full open label data set was not part of the standard work for the clinical trial; it appeared that the investigators had previously discussed the initial OLP data. According to the minutes, outputs of the advisory board appeared to be what would be expected in a published outcome of a clinical trial rather than requiring an advisory board. The Panel further queried whether a paid advisory board was the right forum for presenting the results of the *post-hoc* analysis requested by the investigators.

The Panel noted that according to the agenda, the UK Advisory Board held in the UK on Friday, 25 and Saturday, 26 January 2019 started with registration at 2pm, the meeting started at 2.30pm finishing at 5pm on the Friday and from 9am-1pm on the Saturday. The Panel noted that the reasons given for starting the meeting on the Friday afternoon and finishing it the following day was to maximise attendance and allow health professionals to complete morning clinics and cater for international participants. The Panel noted that it appeared from the agenda that the total time spent on presenting was 2 hours compared with 3 hours and 50 minutes gaining feedback and queried whether this was sufficient. There was no reference in any of the documentation to pre-reading. The summary table provided by Britannia referred to

payment for one hour of preparation time but there were no details of what this entailed. There were 13 advisers and 7 Britannia staff in attendance over the two days. There were no minutes.

According to the MAF, the US Apomorphine Infusion Introduction Advisory Board held on 21 September 2019 had 7 advisors (including an attendee from the UK who also presented a session) and 5 Britannia staff were to attend which was different to that submitted by Britannia in the summary table above. The MAF form had an effective date of 22 February 2019 and stated that the meeting was to be held in Nice, France. The presentation (65 slides) stated that the meeting would run from 10am to 4.30pm. From this agenda the time spent on presenting was 1 hour 10 minutes with 3 hours 55 minutes spent on discussion. Presenters were paid for preparation and attendance time. The MAF form stated that no pre-reading was required for this advisory board. The advisors were paid for attendance time. Minutes were said to be prepared but were not provided to the Panel.

According to the MAF for the Scientific Advisory Board: Update consensus paper and potential for further research which was held on 24 and 25 January 2020 in the UK. Advisors were asked to complete a pre-meeting questionnaire (copy provided). The advisors' responses would then be collated, presented and used as the basis for discussion and to gain consensus for each question. It appeared that six papers were sent as a mandatory pre-read: Pedro Barbosa; AM IMPAkT; Toledo; Opti pump; EuroINF; and Amyloid Apo. The pre-meeting work was expected to take 1 hour 30 minutes. From the agenda on the presentation, the meeting started on Friday with arrivals and lunch at 12pm, with the actual meeting starting at 1pm and finishing at 6pm and then continuing on the Saturday from 8.30am to 12pm. In total, the meeting included 1 hour 45 minutes presentation time (62 slides) and 6 hours discussion time. There were 15 advisors and 5 Britannia attendees. There were differences between the MAF and other details provided by Britannia. For example, from the table provided by Britannia it appeared that the advisors were paid for an additional hour of pre-reading. There were no minutes for this meeting.

According to the MAF for the Optimising PD patient care: Shaping current and future patient pathways for apomorphine advisory board held on 7 and 8 February 2020 in the UK, the same six papers as described above were sent out as a mandatory pre-read. The meeting ran from 1pm to 6pm on the Friday and from 8.30am to 12pm on the Saturday. The pre-meeting work was expected to take 2 hours 30 minutes. From the agenda on the presentation, the meeting started on Friday with arrivals and lunch at 12, with the actual meeting starting at 1pm and finishing at 6pm that day and then continuing on the Saturday from 8.30am to 12pm and included 1 hour 15 minutes presentation time (67 slides) and 6 hours 30 minutes discussion time. There were 12 advisors and 5 Britannia attendees. There were no minutes for this meeting.

According to the MAF for the international nursing approach to optimise PD patient care by defining patient pathways for apomorphine advisory board held on 28 and 29 February 2020 in the UK, 14 advisors and 6 Britannia staff attended, and the meeting ran from 1pm to 6pm on the Friday and from 8.30 to 12pm on the Saturday. There was no mention of pre-reading. From the agenda on the presentation, the meeting included 1 hour 15 minutes presentation time (36 slides) and 6 hours 30 minutes discussion time. There were 14 advisors and 6 Britannia attendees. There were no minutes for this meeting.

It appeared that there had been a lot of activity following the publication of the TOLEDO study. This was not, in itself, necessarily unacceptable under the Code but the Panel had concerns about the overall impression given by the advisory boards.

In summary, the Panel was concerned that for some meetings the proportion of time on the agenda allocated to presentations did not appear to allow adequate time for discussion. Feedback from the participants should be the main focus of advisory boards and only a small proportion of the time should be spent on company presentations. In this regard, the Panel noted that SOP CO40V01 Advisory Boards, effective 22 February 2019, (applicable to Advisory Boards run in September 2019 and all boards in 2020) clarified that the proportion of discussion time compared with presentation time should usually be 70% and 30% respectively and queried whether this was sufficient.

The Panel noted Britannia's submission that, in some situations, advisors were proposed jointly between the medical and marketing teams using their combined knowledge from working for many years in the therapy area.

The Panel further noted Britannia's submission that a senior medical employee had attended two of the six advisory boards and certified the MAF and materials for all meetings and would clearly not have done so if he/she considered that the meetings were promotional. According to Britannia, the signatories operated autonomously and were freely able to insist on changes being made when needed to ensure the meetings were run in a compliant manner.

The Panel noted Britannia's submission that the minutes, when written, where the views of specific advisors were documented, were not shared with sales staff but the advice solicited was clearly used to formulate strategic plans and marketing plans for the business and hence must be shared within the marketing/medical team.

The Panel was also concerned regarding the number of advisors and the ratio of Britannia staff to advisors at some meetings, the lack of pre-reading for some of the meetings given their purpose, the lack of chair and staff briefing and that minutes were not always prepared. It appeared that preparation time was paid when there was no pre-reading (25, 26 January 2019 advisory board).

Given all these concerns, the Panel considered that Britannia had failed to maintain high standards in relation to the advisory boards in general and a breach of Clause 9.1 was ruled.

Although the Panel had concerns, noted above, and ruled a breach of Clause 9.1, it did not consider that these concerns also warranted a ruling of a breach of Clause 23. It also noted that the complainant had provided limited evidence to show, on the balance of probabilities, that the arrangements were unacceptable as alleged. The Panel therefore ruled no breach of Clause 23.1 and consequently no breach of Clause 18.1.

The Panel did not consider that the complainant had provided evidence to show that medical and compliance employees were pressured into approving the meetings or that there was a culture of non-compliance within the company as alleged. The Panel therefore ruled no breach of Clause 9.1.

On balance, the Panel did not consider that the complainant had provided evidence to show that the circumstances warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure.

APPEAL FROM THE COMPLAINANT

The complainant appealed the Panel's rulings of no breach of Clauses 23 and 2.

Selection of Advisors

The complainant stated that Britannia did not have a stand-alone medical affairs team when he/she was an employee (complaint timelines). Therefore, it was inaccurate to imply that the link with experts within PD had been long established within the medical department given the arrangements at Britannia. The company also stated the process of selection of advisors was straightforward but had failed to list out its criteria for selection. The individuals chosen to attend the advisory boards were health professionals that regularly prescribed or had been advocates for Britannia.

The complainant alleged that if the advisory boards were there to aid with strategy, why were minutes not taken and shared with the rest of the cross functional team? Would minutes not have been useful for when the medical employee was not present at the meetings. How would medical affairs know which actions to take following the advice provided by the consultants? It would seem that Britannia was stating that all advice was only relevant to the commercial department (marketing & sales).

Additional information requested

The complainant alleged that the lack of a formal briefing of the advisors was concerning. Britannia stated advisors acting as moderators or facilitators were briefed on their role either on site prior to the start of the meeting or by phone. If this was a speaker meeting, the speakers would be briefed beforehand on their roles and expectations before the start of the meeting. It seemed illogical to have a less robust process for such a high-profile meeting involving multiples KOLs. How would the moderators/ facilitator prepare adequately or have their payments (which the complainant presumed were more than just the 'normal' attendees) justified if they were instructed 'on the spot'. Who provided the briefing to the advisors? Were these individuals within the commercial team (marketing & sales) specifically when the medical employee was not present?

The complainant was concerned that Britannia had stated that the number of individual staff involved in advisory boards was very small, and briefing documents had not been necessary. The complainant alleged that it was important that the Appeal Board be made aware that all the Britannia employees that attended the advisory boards worked in the commercial function (reporting to global commercial and business development), apart from the medical employee. Therefore, for the meetings that the medical employee was not present, did the individuals in the sales and marketing teams perform non-promotional tasks? If their job descriptions were promotional in nature, the complainant alleged that all tasks carried out by the individuals concerned were promotional. Moreover, the advisory boards were driven, organised, conducted by individuals within or reported to the head of sales and marketing. How would individuals within the Britannia sales and marketing team understand their limits/involvement at these

meetings without the appropriate internal briefings? Britannia had not outlined the role its medical employee played during the advisory boards, which was minimal.

Lack of independent scrutiny

The complainant was disappointed regarding the drafting of the response to the complaint and details were provided.

The complainant alleged that he/she would have expected Britannia's parent company (STADA) to carry out the appropriate investigation in regard to this complaint, as there were allegations concerning members of the management team. By having the medical employee that certified these meetings, respond to the complaint, meant that Britannia had not done a thorough investigation. The complainant stated that he/she acknowledged that allegation would be hard to prove. He/she strongly believed that an independent assessment was not carried out by the company, in and of itself spoke volumes of the compliance culture at Britannia or the seriousness the management team viewed such allegations.

Lack of full disclosure

The complainant alleged that during a review of the enclosures, he/she was disappointed to note that Britannia had not provided the Panel with the full context of the organisation and intent of the advisory boards. The advisory boards were planned by the marketing and sales department and appeared in strategic brand plans. The advisory boards fell under the EVOKE series of meetings to aid with health professional engagement. Senior leaders within the organisation were very clear on the context of the advisory boards, and their true intent. All aspects of the logistics, planning, invitations, timings were done by the commercial team. The medical team certified the meetings, and by Britannia's own admission only attended two meetings.

The complainant accepted that some of the advisory boards in regard to the discussion of new data could be warranted. However, the complainant did not agree that a series of meetings planned in advanced for the upcoming year, with provisional set dates and plans which sat within marketing and sales would be considered purely non-promotional. The perception it left, with the casual observer, was that the meetings were promotional, like a series of promotional speaker meetings. Did the medical employee actively plan for these advisory boards? Were the advisory boards part of the medical affairs' plans?

The complainant alleged that Britannia had not provided the Panel with the full context or its true intention for organising such meetings. In doing so Britannia had attempted to mislead the Panel possibly in part to escape a breach of Clause 2.

In summary, given the above reasonings, the complainant appealed the Panel's rulings of no breach of Clauses 23.1 (not representative of genuine consultancy, in the context of advisory boards) and 2 (bringing discredit to the industry by not providing the Panel with all the necessary facts).

The complainant requested copies of the following from Britannia:

- job descriptions for all the Britannia employees that attended the advisory boards
- the brand plans for the sales and marketing teams for the years associated with the advisory boards

- the senior medical employee's briefing of his/her role
- the medical affairs plans that detailed the advisory boards
- rationale for overpayments when no pre-reads were sent out to advisors.

After being provided with a copy of the enclosures to Britannia's response to the complaint that had not been previously provided, the complainant provided further reasons for appeal.

Selection of Advisors

The complainant stated that Britannia did not have a stand-alone medical affairs team when he/she was an employee. Therefore, it was inaccurate to imply that the link with PD experts had been long established within the medical department.

The complainant noted that Britannia stated that the selection of advisors was straightforward but failed to list out its selection criteria. How did Britannia ensure that advisors chosen by other companies, fulfilled its criteria of selection? For example, the advisory board on 7 and 8 February 2020 had advisors from around the globe. How did Britannia ensure that the advisors proposed by other companies (Britannia did not have affiliates) meet the rigour required to participate in a such a meeting?

If the advisory boards were there to aid with strategy why were minutes not taken and shared with the rest of the cross functional team (medical affairs, research and development)? Would minutes not have been useful for when the medical employee was not present at the meetings. How would the medical affairs department know what actions to take following the attendees' advice? It would seem that Britannia was clearly stating that all advice received was only relevant to and for the commercial department's action (marketing & sales). However, this could not be true as advice on clinical trials were sought for the meetings of 24 and 25 January 2020, 7 and 8 February 2020, and 24 and 25 February 2020.

Additional information requested

The complainant alleged that the lack of a formal briefing of the advisors was concerning. Britannia stated advisors acting as moderators/facilitators were briefed on their role either on site before the start of the meeting or by phone. If this were a speaker meeting, the speakers would be briefed beforehand on their roles, not minutes before the meeting. It seemed illogical to have a less robust process for such a high-profile meeting involving multiples global KOLs. How would the moderators/facilitators prepare adequately or have their payments (which he/she presumed were more than just the 'normal' attendees) justified if they were instructed 'on the spot'? Who provided the briefing to the advisors? Did individuals within the commercial team give the moderators/ facilitators a briefing when the medical employee was not present?

The complainant was also concerned that Britannia had stated that the number of individual Britannia staff involved in advisory boards was very small, and briefing documents had not been necessary. The complainant stated that it was important that the Appeal Board be aware that all the Britannia employees who attended the advisory boards worked in the commercial function (reported to the global commercial and business development director), apart from the medical employee. Therefore, during the meetings that the medical employee was not present, did the individuals in the sales and marketing teams perform non-promotional tasks? If their job descriptions were/are promotional, he/she would state that all tasks carried out by the individuals concerned were promotional. Moreover, the advisory boards were driven,

organised, conducted by individuals within or who reported to the head of sales and marketing. How would individuals within the Britannia sales and marketing team understand their limits/involvement at these meetings without the appropriate internal briefing documents? Was it normal for individuals in promotional roles to carry out non-promotional functions in Britannia?

Lack of independent scrutiny

The complainant referred again to the preparation of the response.

The complainant alleged that he/she would have expected Britannia's parent company (STADA) to carry out the appropriate investigation regarding this complaint, as there were allegations concerning members of the management team. The complainant did not believe that Britannia had done a thorough independent investigation. The company did not carry out an independent assessment, and by carrying on in this fashion spoke volumes of the compliance culture at Britannia or the seriousness the management team viewed such allegations.

Lack of full disclosure

The complainant stated that during a review of Britannia's enclosures and files, he/she was disappointed to note that Britannia had not provided the Panel with the full context of the organisation and intent of the advisory boards. The complainant alleged that the advisory boards were planned by the commercial team and featured in their strategic marketing brand plans. The advisory boards were part of the EVOKE series of meetings to aid with health professional engagement. Senior leaders within the organisation were very clear on the advisory boards' context and their true intent. The commercial team did all aspects of the logistics, planning, invitations, timings. The medical employee by Britannia's admission only attended two meetings.

The complainant accepted that some of the advisory boards regarding the discussion of new data could be warranted. However, he/she did not believe that a series of meetings (EVOKE) planned in advanced for the upcoming year, with provisional set dates and plans which sit within the commercial team could be considered purely non-promotional. The perception it left, with the casual observer/ within the organisation, was that the meetings were promotional, like a series of promotional speaker meetings. The complainant stated that he/she had added additional information and concerns on some of Britannia's advisory boards. Did medical direct or actively plan the advisory boards? Were the advisory boards part of the medical affairs' plans?

The complainant was concerned that Britannia had not provided the Panel with the full context or its real intention to organise such meetings. By not providing the Panel with full and frank disclosure, the complainant alleged that Britannia had attempted to mislead the Panel possibly in part to escape a breach of Clause 2.

In summary, given the above reasonings, the complainant appealed the Panel's rulings of no breach of Clauses 23.1 (not representative of genuine consultancy, in the context of advisory board's) and 2 (bringing discredit to the industry by not providing the Panel with all the necessary facts).

The complainant also requested copies of the brand plans for the commercial team detailing the EVOKE meetings.

The complainant provided a chart summarising the general concerns for each meeting.

RESPONSE TO APPEAL FROM BRITANNIA

Britannia submitted that it had nothing further to add in relation to the selection of advisors.

Britannia submitted that official minutes were provided with its original response for the TOLEDO Advisory Board held on 9 January 2019. During the preparation of its response to the complainant's appeal, Britannia located an internal summary booklet (copy provided) for the advisory boards held on 24/25 January 2020, 8/9 February 2020 and 28/29 February 2020. Unfortunately, the booklet was missed in the first submission and Britannia apologised for this.

Britannia submitted that the summary booklet was intended to be used internally only in order to provide the relevant departments with an informal output of the advisory boards, which included the ideas presented by the advisors as to how patient care could be improved. This summary booklet was created as a summary to official minutes, as these would not be shared further than the medical and marketing departments (as per SOP CO40). This summary booklet which was certified for internal use only and was shared with the relevant departments (including medical employees).

Additional information requested

Britannia submitted that as stated in its response to the complaint, certified briefings for employees were not deemed necessary for the advisory boards in question but those included were already experienced in management of these advisory boards. Britannia appreciated the complainant's comments; an employee briefing would have been beneficial to ensure that those in attendance were aware of their individual involvement and responsibilities. The individuals present at the advisory board meetings in question carried out the necessary duties; including the briefing of advisors/facilitators as required.

Britannia stated that it was committed to driving its internal compliance culture and as such at the beginning of 2020 recruited staff. Details were provided which included work to ensure. that all processes, SOPs and systems were compliant and fit for purpose.

Compliance had implemented changes relating to employee briefings and deemed that employee briefings were necessary and was a requirement laid out in its updated internal processes and SOPs. The advisor/facilitator briefing process was outlined in Britannia's response, and it had nothing further to add on this matter.

Britannia submitted that the advisors and facilitators were paid based on fair market value (FMV). Britannia had audited and discovered that there was one example whereby preparation time was paid however no pre-read was issued to the attendees, and this appeared to be human error. Britannia stated that it was committed to this not happening again by ensuring Britannia had robust processes internally, it would update the existing SOP (CO40) and be providing in depth training to the relevant departments.

For the other advisory boards, it was clear from the table submitted within Britannia's original response, that the attendees were expected to complete questionnaires and undertake pre-reading of clinical trials ahead of the meetings and thus the preparation time was warranted and fair.

Lack of Independent Scrutiny

Britannia submitted that certain employees and STADA had awareness of the case.

Lack of full disclosure

Britannia submitted that the advice sought from each advisory board was clearly outlined in its response to the complaint and the *bona fide* need for advice was also included in detail.

Britannia submitted that 'EVOKE' was an expert neurology panel focused on three key topics, 1: evolving landscape for new Parkinson's products, 2: improving the delivery of Britannia's Parkinson's medication through service provision, 3: evaluating clinical data and publication opportunities. The aim of this program was to collaborate with international KOLs, national consultants and nurses to improve the lives of Parkinson's patients. This collaboration was initiated by way of three advisory meetings (24/26 January, 7/8 February, 28/29 February) in which the advice sought was outlined in the table below (adaptation from the table submitted within the original response dated 21 May 2020).

Date of Meeting	Title of Advisory board	Summary of Advice sought
24-25 January 2020	Scientific Advisory Board: Update Consensus	• Review of results of pre-meeting questionnaire • Update a 2015 consensus paper to consider the positioning of apomorphine in the context of new evidence • To consider the future of treatments in PD and determine clinical studies needed for apomorphine to address real world settings
7-8 February 2020	Optimising PD patient care: Shaping current and future pathways for apo- morphine	• Defining the value of PEN vs continuous dopaminergic stimulation (CDS) in the patient pathway • When should patients move from one to the other? • What measures should Britannia put in place to ensure pen patients are switched to CDS in a timely manner? • Defining patient profiles for pen and pump patients • Defining position of apomorphine in relation to other CDS options available • What can Britannia do to enable patients to continue on apomorphine therapy and prevent pump fatigue? • Where is the future of PD treatment?

28-29 February 2020	An international nursing approach to optimise PD patient care by defining patient pathways for apo-morphine	From a nursing perspective: • What is typical profile of a pen and pump patient? • What proportion of patients selected for pen/pump patients are in fact suitably treated? And how could patient selection be improved? • What are the common reasons patients discontinuing pen/pump and can anything be done to pre- vent this? • Would improvement in patient education help with patient retention? • How can Britannia ensure nurses caring for PD patients are best placed to optimise patient care?

Britannia submitted that in preparation for its response, the company had located the 2019 and 2020 brand plans referenced by the complainant in which 'EVOKE' was mentioned. Britannia had included the relevant pages from the 2020 brand plan relating to 'EVOKE'. Britannia stated that it was unable to provide a rationale as to why these brand plans were not included in the first response.

Britannia submitted that the 2020 brand plans include an introduction to 'EVOKE' and the intent of the program (slides 10-11), the project was also included in the 5 year and strategic plans. A key priority of 2020 was to shape global guidelines and the 'EVOKE' project was considered strategically imperative to this priority (slide 6). The events plan for 2020 (slide 9) demonstrated the plans for the project, however due to the pandemic no meetings/congress were held after February 2020.

Britannia submitted that there was no mention of 'EVOKE' within the 2019 brand plans and given the commercially sensitive nature of the material Britannia had not included these.

Britannia submitted that it had made it clear within its response to the complaint that the medical employee did not actively plan the aforementioned advisory boards. The meeting approval forms provided as part of Britannia's original response clearly stated the job titles of the individuals leading on the meeting and it was clear from these documents that the individuals belonged to the sales and marketing department; however the medical employee would, as part of Britannia's internal process SOP CO34, been privy to the meeting details from the concept stage as initial approval was required to progress an advisory board. The medical employee and compliance also (as previously disclosed) certified all aspects of these advisory boards. Britannia stated that it did not have any medical affairs plans.

Summary

Britannia submitted that it was committed to its compliance responsibilities and had provided the context and intent for these advisory boards to the Panel and complainant by way of the documentation previously supplied. There had been no attempt made to mislead the Panel or complainant.

With reference to the documentation requested by the complainant, Britannia had enclosed the documentation it felt were suitable to share. Britannia had not included the job descriptions nor certain material which was not necessary in its response.

Britannia submitted that, as it had explained within its response to the complaint, it had no rationale for the payment of preparation time to a consultant when it was not required nor were Britannia able to provide the medical affairs plans as none were prepared for the timeframe concerned.

FINAL COMMENTS FROM THE COMPLAINANT

The complainant stated that he/she would address Britannia's response with his/her comments concerns.

Selection of advisors

The complainant alleged that it was evident from the evidence presented, Britannia had some criteria for selecting advisors. These criteria were made clear in the summary booklet (page 3) in the first paragraph 'in Q1 2020, three consecutive scientific advisory boards were held with three separate international expert groups – key opinion leaders, experienced neurologist, and Parkinson's nurses- **representing many of Britannia's key customers and APO-go prescribers**'. Part of Britannia's selection process was to have attendees that were either key customers or Apo-go prescribers.

The complainant alleged that in the 'complete' 2020 brand plan (this was explained further under lack of full disclosure) on slide 36, it was possible to have insight into the selection criteria for some of the advisors:

- EVOKE KOLs: Partner with key KOLs [named] to attend this event to ensure continued relationships in key accounts threatened by competitor activity
- EVOKE Rising Stars: Continue to support up and coming KOL [named] for long term relationship with MOVAPO business
- EVOKE Nurse Ad board: Continue to partner with key PD Nurse to invest in MOVAPO business.

The complainant noted these were not UK customers, but highlighted the point that Britannia had a selection criterion for its advisory boards but was reluctant to share (lack of transparency).

The complainant alleged that Britannia had chosen not to comment on the selection criteria to identify and engage the health professionals for its advisory boards, even though the documentation Britannia provided indicated a selection process.

Lack of full disclosure

The complainant noted that Britannia had managed to locate the summary booklet and associated brand plans that mentioned the EVOKE advisory boards on this occasion. The complainant alleged that this discovery was not in keeping with Britannia's initial response stated that there were not official minutes or marketing plans that would have provided the Panel with the full context of the meetings.

The complainant alleged that the summary booklet was mentioned in his/her complaint in April 2020. The complainant was disappointed that Britannia continued to mislead by stating that the booklet was a summary of the official minutes. Page 3 of the booklet stated '…This document summaries some of the key points arising from each of the meetings. Full reports were available on request from a named manager…'. The complainant queried where were the full reports/ minutes and why Britannia had not supplied this information to the Panel?

The complainant noted that EVOKE was Britannia's KOL management programme. He/she was unclear why Britannia was attempting to call it an expert neurology panel, thereby giving it a non-promotional feel? The complainant alleged how could a panel, set up in advance, and ready to provide strategic direction, if the organisation itself was not aware of the areas it required advice on? Why did Britannia not provide the Panel with all information regarding EVOKE during its first response? It was easy for Britannia to state there was no rationale on the decision not to include the brand plans during the first response. What oversight/checks were in place when Britannia was drafting the original response?

The complainant alleged that Britannia had failed to provide the Panel with the full 2020 brand plan (provided). In Britannia's submission, it would seem that there were only 10 slides in which EVOKE was mentioned. In the full 2020 brand plan, EVOKE was mentioned in 20 slides. The complainant listed the slide numbers and noted when EVOKE was mentioned. The full brand plan left the reader with the following impression:

- The commercial side of the business was solely responsible for strategic and delivery of the brand plan (including advisory boards).
- There were no medical affairs plans or involvement.
- Individuals within the sales and marketing team were responsible for delivering on EVOKE.
- There was a selection criterion for specific health professionals to attend the advisory board meetings.
- EVOKE was a KOL development programme in the guise of advisory boards.
- The advisory boards were treated as speaker bureaus.

The complainant noted that Britannia had stated that 'there was no mention of EVOKE within the 2019 brand plan and it had not included these'. The complainant alleged that this was not accurate. In slides 23 and 24 of the full 2020 brand plan, EVOKE was mentioned in US activities and in UK activities.

The complainant alleged that the heading of both slides focuses on marketing-led activities year to date 2019. This evidence suggested that EVOKE meetings took place in 2019. Britannia had not disclosed this to the Panel – why?

<u>Additional Information requested</u>

The complainant noted that Britannia had stated that promotional employees (in the sales and marketing department) regularly organised and ran advisory boards. Britannia had failed to provide job descriptions of its employees who arranged and organised these advisory boards. Could Britannia confirm that the employees concerned had sales targets and only promotional outcomes/activities/deliverables in their job descriptions? If yes, how could individuals be

expected to run entirely non-promotional activities without appropriate internal briefing documents? Where was the involvement of medical affairs?

Britannia claimed that it was committed to driving its internal compliance culture, but the complainant alleged that Britannia had left out pertinent and important information to the Panel. This was not in keeping within the spirit of the Code. Britannia had failed to provide further comment on sections that were raised previously:

- Selection of advisors.
- Advisor/facilitator briefing process.
- The medical employee's change of duties.

The complainant did not accept Britannia's submission regarding the attendance of the medical employee at the advisory boards.

Bona fide advice

In the complete 2020 brand plan on page 33, the following was noted:

KEY ISSUES	STRATEGIC IMPERATIVES	CRITICAL SUCCESS FACTORS
1 Development of HCPs to drive higher base of patients that are ready to move onto Apo go therapy. 2 This included patient education and HCP/Trust responsibility for follow up care	• Educational meetings focus on patient selection and education, i.e. preparing a pull through of patients • Clinical sell v service sell	▪ EVOKE uptake and aligned KINETIC coverage for all KOLs identified ▪ Masterclass and International Congress development plan, all KOLs to be supported through 1 educational event 2020 ▪ ICE scores to drive clinical engagement and all KAMs move 1 point score through ADVANCE on clinical selling 2020 ▪ Patient education framework to be identified through LHEs and developed through NAA/KAM interaction at local level ▪ PRM to be delivered by UK team Q4 with Patient Case studies

The complainant questioned if Britannia could confirm if EVOKE was used to develop health professionals, and the manner described above? For clarity's sake, could Britannia confirm that tactic used to achieving its strategic imperatives was to organise advisory board/ educational meetings (preparing a pull through of patients)? If this was the case, did it constitute a *bone fide* reason to hold multiple advisory boards?

The complainant alleged that when he/she was an employee, the EVOKE programme was described as a speaker bureau, with multiple meetings planned during each segment. This was

evidenced by the summary booklet (three consecutive meetings in Q1) and the 2020 brand plan (slide 97). Britannia had not commented on the frequency of such meetings. In addition, what *bone fide* advice was required on products that had had marketing authorisations granted in 2000 (Pre-filled syringes) and 1999 (Pen) respectively? Could Britannia provide further explanation of the frequency of the advisory boards (three in Q1 2020 with a repeat in Q2 & Q3)? What emerging data could warrant multiple meetings per quarter, when separate meetings had already discussed emerging data (TOLEDO)?

Summary

The complainant was disappointed that Britannia had failed to provide the Appeal Board with all the necessary information during its first and second response to the Panel.

The complainant appreciated that the advisory boards were certified. However, the complainant alleged that certification did not explain inaccuracies, lack of transparency or dressing up promotional meetings as advisory boards. Britannia had attempted to mislead the Panel possibly in part to escape a breach of Clause 2. Given the above reasonings, he/she appealed the Panel's ruling of no breach of Clauses 23.1 (not representative of genuine consultancy, in the context of advisory boards) and 2 (bringing discredit to the industry by not providing the Panel with all the necessary facts/information).

The complainant noted and provided a list of the instances in the complete 2020 Brand Plan, when EVOKE was mentioned.

APPEAL BOARD RULING

The Appeal Board noted that the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties.

The Appeal Board was concerned about Britannia's deviation from its SOPs for advisory boards including (i) that commercial staff were present as observers without any clearly defined role and (ii) that the maximum number of advisors was exceeded on a number of occasions without proper recording or investigation of that deviation. The Appeal Board noted from the representative from Britannia that commercial staff were responsible for the logistics of the advisory board meetings. The Appeal Board noted that whilst the involvement of and attendance at advisory boards by commercial staff was not necessarily unacceptable, the external perception of such was important.

The Appeal Board was very concerned that Britannia had not provided all the documents to the Panel: certain materials were only provided for the appeal. In that regard the Appeal Board noted that in response to the complainant's appeal, Britannia had provided an internal summary booklet for the advisory boards held on the 24/25 January 2020, 8/9 February 2020 and 28/29 February 2020. The Appeal Board was concerned that this was a summary only, queried why it was not provided to the Panel and considered that no satisfactory explanation was given. The Appeal Board was concerned about a lack of detailed minutes for the advisory boards and that in some instances there were no minutes at all. The Appeal Board noted that Clause 23.1 required the company to maintain records concerning the services provided by consultants. The Appeal Board queried how, without such record keeping, appropriate use was made of the advisors' input in the advisory board meetings at issue as required by Clause 23.1.

The Appeal Board noted that Britannia had provided selected slides from its 2020 Brand Plan whilst the complainant appeared to have provided the full version. The Appeal Board noted that whilst this was an internal document, it had concerns around the use of commercial terminology when discussing advisory boards. For example, Evoke was listed as a Strategic Objective (key performance indicator (KPI)) under 'What? Tactic description' with the 'How? Tactic description' described as '2-3 ad boards per year for intl. KOLs, rising stars & nurses'. The representative from Britannia at the appeal agreed that this was poorly worded and was in the incorrect place within the brand plan; Britannia had updated its SOP and brand plan as a result of this case.

The Appeal Board noted its comments and concerns above and considered that the arrangements for the advisory boards at issue were such that the requirements under Clause 23.1 were not met and it thus ruled a breach of that clause. The appeal on this point was successful.

[Post meeting note: it was noted that the complainant had not appealed the Panel's ruling of no breach of Clause 18.1 and the Appeal Board did not discuss this clause as its remit was limited to clauses under appeal. The supplementary information to Clause 18.1 stated that any payment to an individual for an activity that was ruled in breach of Clause 12.2 and/or Clause 23 was likely to be viewed as an unacceptable payment and thus in breach of Clause 18.1.]

The Appeal Board noted Britannia's submission that where minutes of advisory board meetings were written where the views of specific advisors were documented these minutes were not shared with sales staff. The advice solicited was clearly used to formulate strategic plans and marketing plans for the business and hence had to be shared within the marketing/medical team.

The Appeal Board noted the Panel's comments and its ruling of a breach of Clause 9.1 of the Code which Britannia had accepted.

Despite its concerns the Appeal Board considered that it had not been established, on the balance of probabilities, that the Britannia advisory boards at issue did not include legitimate content or that legitimate business questions were not being addressed.

Although concerned about the arrangements for the advisory boards, the Appeal Board did not consider that the circumstances in this case amounted to a breach of Clause 2 which was a sign of particular censure and was reserved for such use and it upheld the Panel's ruling of no breach of Clause 2. The appeal on this point was unsuccessful.

Complaint received **23 April 2020**

Case completed **20 April 2021**