CASE AUTH/3505/4/21 ***NO BREACH OF THE CODE***

COMPLAINANT v BRITANNIA

Concerns about advisory boards and nursing service

An anonymous ex-employee complained about Britannia's advisory boards for Lecigon (levodopa/carbidopa/entacapone), a new intestinal gel therapy for advanced Parkinson's disease and nursing service.

The complainant stated that not all staff were aware of a previous complaint about Britannia advisory boards and it would make sense for employees to have an awareness so that mistakes were not repeated. He/she assumed the lack of transparency was so that profitable practices were continued, although not compliant.

The complainant alleged that when preparing the UK plans for the Lecigon launch, his/her colleagues in sales and marketing planned advisory boards, with minimal medical input, branded the advisory meetings as 'EVOKE' (a marketing term) and arranged multiple meetings when one would do. Further alleging that the company attempted to use the key account managers for advisory board facilitation and involvement in a multinational clinical trial to build advocacy.

The complainant stated that he/she had also raised concerns that Britannia's nursing service was compromised by associating closely with the sales team. The sales team was planning on using data from the nursing service to enable sales/targeting for Lecigon (as part of the UK brand plan). This was already the case for APO-go.

The nursing platform was under the administration of the sales function rather than entirely within medical to prevent any possible compromise (perceived or otherwise) of patient data.

The complainant stated that he/she was concerned that his/her ex-employer did not take the Code or patient data seriously. He/she was also confused about the intent of not disclosing challenges and informing the broader organisation of any lessons learned. The complainant proposed that the PMCPA invite Britannia's management to comment on the lack of compliance and adherence to the Code.

The detailed response from Britannia is given below.

The Panel noted the submission from Britannia as to the reasons for the advisory boards. The Panel then went on to consider the arrangements relevant to the allegations for each of the two advisory boards.

The Panel noted that Lecigon was a new product for Britannia. It was described as a new gel formulation therapy for people with Parkinson's disease which was a therapeutic area where Britannia already had products.

Turning to the allegations made by the complainant, the Panel did not consider it was necessarily a breach of the Code if all staff were not aware of a previous relevant case as alleged. Clearly a company ruled in breach of the Code needed to provide the requisite

undertaking and take all possible steps to avoid a similar breach of the Code in the future. Britannia submitted that it had provided details of the previous case to all relevant staff.

Britannia provided a copy of the launch plans which it stated were created by sales and marketing and explained that during its internal interviews there was reference made to an employee previously employed in medical being involved with the development, however, it was unable to confirm this involvement as the individual was no longer an employee.

With regard to the number of advisory boards, the Panel noted that the Medical Marketing Lecigon launch plan referred to a further two advisory boards but there was no evidence before the Panel with regard to whether these advisory boards had or were still to go ahead. The Panel noted Britannia's submission that it had held two advisory boards in 2021 related to Lecigon which were justified as insights were required from both payors and key opinion leaders.

With regard to the complainant's concern that colleagues in sales and marketing began planning advisory boards, with minimal medical input, the Panel noted Britannia's acknowledgement that the presence of the proposed advisory boards within the Lecigon launch plans could be construed as being sales and marketing led and as such it had not maintained high standards in breach of the Code. The Panel noted, however, that it was not necessarily a breach of the Code to plan advisory boards with minimal medical input as alleged. The Panel noted Britannia's submission that there was sales and marketing involvement in the early meetings regarding defining insights required, however, once these insights and objectives were defined, these individuals no longer attended any project meetings. The Panel noted Britannia's submission that advisory board meetings initially proposed within the Lecigon internal launch plans were developed and led by medical with compliance oversight.

According to Britannia, the advisory board for payors was led by a Britannia commercial employee as the objective was to gather insight and advice from NHS England payors with regards to the best funding and reimbursement pathway for Lecigon. The advisory board in May 2021 was instigated by a medical employee who had left the company when it was passed to a medical contractor. The Panel further noted Britannia's submission regarding the attendance of various employees including marketing at various meetings including the payors advisory board.

The Panel did not consider that the complainant had established, on the balance of probabilities, that the arrangements for the two advisory boards were unacceptable with regard to the involvement of sales and marketing or the number of advisory boards and thus consultants contracted. No breach of the Code was ruled in relation to each advisory board based on the complainant's specific allegations.

The Panel noted Britannia's submission that it found no evidence of the two advisory boards held being part of the 'EVOKE' series as alleged and that no key account managers were present at either of the advisory boards nor were they involved in the facilitation or organisation of the meetings. The Panel considered that the complainant had not established, on the balance of probabilities, that the advisory board constituted disguised promotion in that regard as alleged and no breach was ruled.

The Panel noted its rulings above and consequently ruled no breaches of the Code including of Clause 2.

With regard to the nursing service, the Panel noted that, again, the complainant had not provided evidence that the nursing service data was compromised.

The Panel noted Britannia's explanation that it used two software solutions, the first was the bespoke Nurse database and the second was the dashboard solution which was used by Britannia's sales and customer service teams. The systems were not interlinked and were independent of each other; users did not have access to both systems.

The Panel was concerned that the service was under the administration of the sales function, with a commercial employee approving requests for users for the nurse database and being the internal budget holder. Britannia acknowledged that this was not ideal and planned to see if it could be reallocated to a member of the medical team to manage. It noted Britannia's submission that the nurse service provided ongoing support to Parkinson's disease patients once they had been selected for Apo-go therapy and that patient data was recorded by the nursing team. Britannia submitted that the nursing service operated independently from the sales team and commercial functions of the business. The Panel further noted Britannia's submission that the sales team did not have access to nor were they able to view or utilise any data from the nurse database to aid targeting. No evidence had been provided to the contrary by the complainant.

The Panel did not consider that the complainant had provided evidence to show that the nurse service was inappropriately associated with the sales team or that the sales team planned on using data from the nursing service to enable sales/targeting for Lecigon (as part of the UK brand plan). The Panel therefore ruled no breaches of the Code including Clause 2.

An anonymous ex-employee complained about Britannia's advisory boards and nursing service.

The allegations included advisory boards for Lecigon (levodopa/carbidopa/entacapone), a new intestinal gel therapy for advanced Parkinson's disease.

COMPLAINT

1 Advisory Boards

The complainant stated that he/she was aware that Britannia received a complaint regarding advisory boards. Not all personnel were aware of the complaint. The complainant stated that he/she was not sure why management had kept it a secret. It would make sense for employees to have an awareness of the company's challenges so that mistakes were not repeated. He/she assumed the lack of transparency was so that profitable practices were continued, although not compliant.

The complainant alleged that when preparing the UK plans for the Lecigon launch, his/her colleagues in sales and marketing did the following:

- began planning advisory boards, with minimal medical input
- branding the advisory meetings as 'EVOKE' (a marketing term)
- arranging multiple meetings when one would do
- attempting to use the key account managers for advisory board facilitation and involvement in a multinational clinical trial to build advocacy.

The complainant stated that he/she suggested that if there were medical specific tactics, these should be colour coded separately, or in a different section to prevent confusion, this suggestion was rejected. It was confusing to pick out which specific actions belonged to medical, sales or marketing.

When writing to Britannia, the Authority asked it to consider the requirements of Clause 12.1 in relation to the alleged branding of the advisory board meeting and role of the key account managers, Clause 23.1 in relation to the number of consultants hired and the allegation that 'multiple meetings were held when one would do' and Clauses 9.1 and 2 in relation to all matters raised in relation to the advisory board meetings.

2 Alleged compromised nursing service

The complainant stated that he/she had also raised concerns that Britannia's nursing service was compromised by associating closely with the sales team. The sales team was planning on using data from the nursing service to enable sales/targeting for Lecigon (as part of the UK brand plan). This was already the case for APO-go.

The nursing platform was under the administration of the sales function. The complainant stated that he/she was not sure why this would be the case, as this should sit entirely within medical to prevent any possible compromise (perceived or otherwise) of patient data.

When writing to Britannia, the Authority asked it to consider the requirements of Clauses 2, 9.1 and 19.2 of the Code in relation to the nursing service.

Summary

In summary, the complainant stated that he/she was concerned that his/her ex-employer did not take the Code or patient data seriously. He/she was also confused about the intent of not disclosing challenges and informing the broader organisation of any lessons learned. The complainant proposed that the PMCPA invite Britannia's Management Committee to comment on the lack of compliance and adherence to the Code.

RESPONSE

Britannia stated that it took the allegations seriously and conducted a full internal investigation into the matter, led by compliance, which included internal interviews where relevant. Details were provided and included commercial and medical staff.
The findings of the internal investigation and interviews had been used to respond to the questions put to Britannia by the PMCPA and the Complainant. Summaries of these internal interviews were provided.

Lecigon Launch Plan

Britannia stated that it had acquired a new product, Lecigon and was currently awaiting the marketing authorisation. Britannia provided a copy of the launch plans which were created by sales and marketing. During the course of its internal interviews there was reference made to a previous medical employee being involved with the development, however, Britannia was unable to confirm this involvement as the individual mentioned was no longer an employee.

The advisory board meetings were initially proposed within the Lecigon launch plans, these were internal plans and the advisory boards held after these plans were drawn up, developed and led by medical with compliance oversight.

These marketing plans were not reviewed by Britannia's compliance officers, the plans were issued on email and then presented on 19 April 2021 to certain company personnel. The details were provided and included senior staff in commercial as well as medical and finance.

Britannia had held two advisory boards in 2021 related to Lecigon and submitted that these were justified as insights were required from both payors and key opinion leaders (KOLs):

Date of meeting	Title of Advisory Board	Meeting Lead	Britannia attendees and role	Objectives
20 April 2021	Lecigon Advisory Board for Payors at NHS England	market access employee	Two marketing employees and two agency employees to moderate and take minutes.	1) Understand which is the best funding and reimbursement pathway for Lecigon. 2) Understand how to access and engage with NHS England. 3) Understand the challenges Britannia could face based on the evidence package built. 4) Understand how pricing decisions are made and what is considered. 5) Gain an understanding of timelines and the decision making process.

Date of meeting	Title of Advisory Board	Meeting Lead	Britannia attendees and role	Objectives
18 May 2021	UK Advisory board for KOLs advising on the launch of Lecigon® into the UK Market. To provide real world insights and guidance for its effective introduction into UK clinics, for advanced Parkinson's patients.	Contracted medical consultant	Two medical staff who had roles, senior staff who were presenting. a marketing employee to manage technical support and did not participate in discussion. An events employee and two agency staff to provide event support and to write a report.	1) Understand where Lecigon will potentially fit within current prescribing for advanced and complex Parkinson's disease in accordance with the licensed indication – when combinations of oral medicines are no longer adequately working. 2) Aid Britannia in developing the launch strategy around the development of a practicable and value-added proposition for patients, healthcare professionals and other stakeholders.

The Britannia advisory board attendees were listed in the above table, there were no key account managers (KAMs) present at either of the advisory boards nor were they involved in the facilitation or organisation of the meetings. The full list of attendees for each meeting could be found in the meeting approval forms (MAF).

Whilst locating materials for this response, Britannia discovered that the MAF (Meeting Approval Form) for the Payors advisory board held on 20 April 2021 was regrettably not formally examined. Britannia provided the draft MAF. The formally examined MAF for the KOL advisory board held on 18 May 2021 was also provided.

The advisors present were selected for their insights and were relevant, proportionate and compliant with Britannia's internal standard operating procedure (SOP).

Britannia stated that during its internal investigation, it had found no evidence to support the allegation that more meetings were held than required nor had Britannia found any evidence of the two advisory boards held being part of the 'EVOKE' series. The 'EVOKE' series of advisory boards were subject of a previous PMCPA case and the terminology has not been used since.

Sales and Marketing involvement

The advisory board in [March] 2021, was led by a Britannia commercial employee as the objective was to gather insight and advice from NHS England payors with regards to the best funding and reimbursement pathway for Lecigon. The advisory board in May 2021, was instigated by a medical employee, upon his/her departure from the company this meeting was passed to a contracted medical consultant.

Britannia stated that from its internal investigation it was clear that there was sales and marketing involvement in the early meetings regarding defining insights required, however once these insights and objectives were defined, these individuals no longer attended any project meetings.

The marketing employee role, meant that he/she was involved in some of the logistical aspects of organisation. The event team were present to aid with event support. The contracted medical consultant advised that there was a discussion held with a marketing employee at initiation of the 18 May advisory board to ensure that they were aligned on what insights were desired, once this was confirmed the marketing employee asked not to attend further meetings, this request was complied with.

Transparency and awareness

Britannia noted the complainant's allegation that details of Britannia's previous complaints were kept a secret, this was untrue. Upon receipt of a complaint, the Britannia management committee was briefed and all relevant personnel were advised of the complaint, Britannia then briefed all relevant employees upon receipt of the Panel's ruling so that Britannia might develop and implement changes committed to. With regard to advisory boards specifically, Britannia's compliance officers had hosted 'Outcomes' sessions, which were initiated on 14 May 2021, for all relevant personnel.

On 24 May 2021, three senior Britannia employee's hosted a 'Company Compliance update' with the entire company to ensure understanding and transparency with regards to the company's concluded PMCPA cases and pending Appeal Board. Details relating to all its previous cases including the advisory board case were included during this company wide meeting.

Britannia stated that it had ensured that any commitments made to the Panel or recommendations received from the Panel in case rulings had been implemented into its SOPs to ensure the internal processes were compliant with the Code and to prevent similar mistakes being made again. CO40 Britannia's internal Advisory Board SOP, was updated to reflect the Panel's ruling in Case AUTH/3335/4/20, this was released to the company on 28 May 2021.

Software

Britannia explained that the software provided by a service provider encompassed many sub-projects under the same brand. Britannia currently used two of these software solutions, the first was the bespoke Nurse database and the second was the dashboard solution which was used by Britannia's sales and customer service teams. The systems were not interlinked, the two systems were independent of each other and users did not have access to both systems.

The dashboard system was used by the sales team and commercial departments only. The system was fed sales data via a report that was created by a Britanniamanager, the report contained data collated from Britannia's internal SAP systems (Financial system), a homecare third party provided and individual buying points. This collated data was fed into the dashboard system to provide a sub-national data overview which was used by the sales and commercial teams to ascertain performance, track sales and view sales trends.

The nurse database was used by the nurse team, the pharmacovigilance team and a medical employee. The system was used to record all interactions with patients; including patient details, medical history, current treatment therapy. The system could auto-generate letters which were stored within the system on the patients record, the system allowed for the nurses to record adverse events directly within the systems which were automatically sent to the pharmacovigilance team. The patient information within the system had been manually added by the Britannia nurse team, the patient details were only accessible to the nurse assigned to the patient and to three nurse managers who required oversight when they were 'on-call'. There was a dashboard within the system that looked at metrics per nurse, this included metrics on home visits, telephone calls, initiations, patients under care. These metrics were only visible to the individual nurse and did not contain any patient information, the data was anonymised.

During Britannia's internal interviews, that a commercial employee approved requests for users for the nurse database and was the internal budget holder Britannia recognised that this was not an ideal situation and would speak with the service provider to see if this could be reallocated to a member of the medical team to manage.

Alleged compromised nursing service

Britannia submitted that its nurse service worked alongside healthcare professionals to provide on-going support to Parkinson's patients once they had been selected for Apo-go therapy. Britannia stated that its nurse service was led by a manager, who reported to medical. The service was independent of the sales team and the commercial functions of the business.

The allegations regarding a 'comprised nurse service' were false. Britannia's nurse service operated independently from the sales team. The sales team had no access to the nurse database nor the data within it. The sales team did not have access nor were able to view or utilise any data from the nurse database to aid targeting.

Summary

Britannia stated that it was committed to transparency and had disclosed all necessary facts to the Panel along with the details and associated materials in relation to the allegations.

As documented above and evidenced by the materials the advisory board meetings were led by market access and medical. Britannia acknowledged that the presence of the proposed advisory boards within the Lecigon launch plans could be construed as being sales and marketing led and as such Britannia agreed that it had breached Clause 9.1 and had not maintained high standards.

Britannia strongly denied breaching Clauses 2, 12.1 and 23.1 in relation to the advisory boards detailed within this response.

Britannia stated that its nurse service was provided to benefit patients and provide support to the NHS, this service was independent of its sales function and its personnel were clear on the separation and agree that there was a clear divide between promotional activities and Britannia's nurse service. Britannia therefore denied breaching Clauses 2, 9.1 and 19.

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 considered the allegations as follows.

1 Advisory Boards

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 relevant to the allegations for each of the two advisory boards.

The Panel noted that Lecigon was a new product for Britannia. It was described as a new gel formulation therapy for people with Parkinson's disease which was a therapeutic area where Britannia already had products.

The Panel noted that according to the MAF for the Payors meeting held on 20 April 2021, the objective of the advisory board was to gain greater understanding of the best funding and reimbursement pathways for Lecigon, how to access and engage with NHS England, challenges

based on the current evidence package, understanding how pricing decisions were made and what was considered and to gain understanding of the timelines and the decision making process. The MAF stated that advisors had not been finally selected yet but listed the job titles of desired participants including: GP and governing body member at named clinical commissioning group (CCG); Chair of a neurological Alliance; NHS commissioning managers; and clinical improvement staff from NHS England.

The MAF indicated that three members of Britannia staff would attend and two from the events company. According to Britannia's response, only two members of staff attended this advisory board and two people from the events company. The Panel noted that the show reel from the advisory board meeting listed three Britannia employees in attendance.

With regard to the KOL Advisory Board meeting held on 18 May 2021, the Panel noted from the MAF that the meeting objectives were to bring together 8 -10 experienced clinicians who were considered KOLs in Parkinson's disease management in the UK, who were experienced in the use of Levodopa-carbidopa gel, worked in secondary care Parkinson's services with equal representation from care of the elderly doctors. Invitees were to ideally involve a UK wide perspective with representation from the devolved nations and to understand where Lecigon would potentially fit within current prescribing for advanced and complex Parkinson's disease in accordance with the licensed indication – when combinations of oral medicines were no longer adequately working.

According to the MAF, seven staff from Britannia were to attend (this included three attendees, two observers from the company, an events contractor observer and an external medical writer).

Turning to the allegations made by the complainant, the Panel did not consider it was necessarily a breach of the Code if all staff were not aware of a previous relevant case as alleged. Clearly a company ruled in breach of the Code needed to provide the requisite undertaking and take all possible steps to avoid a similar breach of the Code in the future. Britannia submitted that it had provided details of the previous case to all relevant staff.

Britannia provided a copy of the launch plans which it stated were created by sales and marketing and explained that during its internal interviews there was reference made to a previously employed medical employee being involved with the development, however, it was unable to confirm this involvement as the individual mentioned was no longer an employee.

With regard to the number of advisory boards, the Panel noted that the Medical Marketing Lecigon launch plan referred to a further two advisory boards; Clinician Ad Board and Nurse Ad Board but there was no evidence before the Panel with regard to whether these advisory boards had or were still to go ahead. The Panel noted Britannia's submission that it had held two advisory boards in 2021 related to Lecigon which were justified as insights were required from both payors and key opinion leaders.

With regard to the complainant's concern that colleagues in sales and marketing began planning advisory boards, with minimal medical input, the Panel noted Britannia's acknowledgement that the presence of the proposed advisory boards within the Lecigon launch plans could be construed as being sales and marketing led and as such it had not maintained high standards in breach of Clause 9.1. The Panel noted, however, that it was not necessarily a breach of the Code to plan advisory boards with minimal medical input as alleged. The Panel noted Britannia's submission that there was sales and marketing involvement in the early meetings regarding defining insights required, however, once these insights and objectives were defined, these individuals no longer attended any project meetings. The Panel noted Britannia's submission that advisory board

meetings initially proposed within the Lecigon internal launch plans were developed and led by medical with compliance oversight.

According to Britannia, the advisory board for payors was led by a commercial Britannia employee as the objective was to gather insight and advice from NHS England payors with regards to the best funding and reimbursement pathway for Lecigon. The advisory board in May 2021 was instigated by a Britannia's medical employee upon his/her departure from the company, this meeting was passed to a contracted medical consultant. The Panel further noted Britannia's submission that the marketing employee role meant that, he/she was involved in some of the logistical aspects of organisation. The event team were present to aid with event support. The contracted medical consultant advised that there was a discussion held with a marketing employee at initiation of the 18 May advisory board to ensure that they were aligned on what insights were desired, once this was confirmed the marketing employee was asked not to attend further meetings, this request was complied with.

The Panel did not consider that the complainant had established, on the balance of probabilities, that the arrangements for the two advisory boards were unacceptable with regard to the involvement of sales and marketing or the number of advisory boards and thus consultants contracted. No breach of Clause 23.1 was ruled in relation to each advisory board based on the complainant's specific allegations.

The Panel noted Britannia's submission that it found no evidence of the two advisory boards held being part of the 'EVOKE' series as alleged and that no key account managers were present at either of the advisory boards nor were they involved in the facilitation or organisation of the meetings. The Panel considered that the complainant had not established, on the balance of probabilities, that the advisory board constituted disguised promotion in that regard as alleged and no breach of Clause 12.1 was ruled.

The Panel noted its rulings above and consequently ruled no breach of Clauses 9.1 and 2.

2 Alleged compromised nursing service

With regard to the nursing service, the Panel noted that, again, the complainant had not provided evidence that the nursing service data was compromised.

The Panel noted Britannia's explanation that it used two software solutions from a service provider, the first was the bespoke Nurse database and the second was the dashboard solution which was used by Britannia's sales and customer service teams. The systems were not interlinked and were independent of each other; users did not have access to both systems.

The Panel was concerned that the service was under the administration of the sales function, with an individual approving requests for users for the nurse database and being the internal budget holder. Britannia acknowledged that this was not ideal and planned to see if it could be reallocated to the medical team to manage. It noted Britannia's submission that the nurse service provided ongoing support to Parkinson's disease patients once they had been selected for Apo-go therapy and that patient data was recorded by the nursing team. Britannia submitted that the nursing service operated independently from the sales team and commercial functions of the business. The Panel further noted Britannia's submission that the sales team did not have access to nor were they able to view or utilise any data from the nurse database to aid targeting. No evidence had been provided to the contrary by the complainant.

The Panel did not consider that the complainant had provided evidence to show that the nurse service was inappropriately associated with the sales team in breach of Clause 19.2 or that the sales team planned on using data from the nursing service to enable sales/targeting for Lecigon (as part of the UK brand plan). The Panel therefore ruled no breach of Clause 19.2 and consequently no breach of Clauses 9.1 and 2.

Complaint received **19 April 2021**

Case completed **21 September 2021**