INTERIM CASE REPORT

An interim case report has been published in this case as the final report was delayed because the Code of Practice Appeal Board had required audits of Britannia Pharmaceuticals Ltd's procedures in relation to the Code (Paragraph 11.3 of the Constitution and Procedure refers).

CASE AUTH/3355/5/20

CONTACTABLE EX-EMPLOYEE v BRITANNIA

Conduct in relation to payments to health professionals, meetings in India, alleged failure to disclose information to the PMCPA and investigator led clinical trials

A complainant complained about arrangements at Britannia Pharmaceuticals UK in relation to a number of matters which were considered as follows.

The detailed response from Britannia is given below.

1 Payments to Health Professionals

The complainant stated that over the last 4 years, Britannia had paid health professionals above the fair market value (FMV), not in keeping with its standard operating procedures (SOPs). The same speakers were used for promotional meetings, presenting almost identical slide sets. The complainant further stated that when compliance refused to sign-off on 'prep time', the speakers (under instruction from Britannia) added in a couple of slides or attended 'briefing meetings' (usually a quick phone call or discussion at the venue) to justify 'prep time' rates. This issue had been raised but no action was taken to stop it.

The Panel noted that Britannia's review of all health professional payments made under consultancy was based on the records that were electronically accessible; the company planned to check its hard copy files once Covid restrictions were lifted.

The Panel noted Britannia's submission that it had reviewed the arrangements from electronic records for the 10 health professionals who were most frequently engaged with Britannia on both global and UK-based projects. Details were provided.

The Panel noted Britannia's submission that it found no evidence of inflated payments to health professionals and the rates paid were in keeping with its standard operating procedures (SOPs) using predetermined internal hourly rates which reflected the consultant's professional status and expertise. The Panel considered that the payment of the same amount of paid preparation time for when the same slides or essentially similar slides were used as that paid when a new presentation developed was unacceptable as the payment was not in relation to the work needing to be done. The Panel was very concerned that Britannia had made payments to health professionals for preparation time where it was not warranted nor required. In the Panel's view, the payments in these instances did not reflect the fair market value of the services provided.

The Panel was further concerned to note Britannia's submission that there were also clear examples of payments having been made to health professionals without a contract in place. It was very concerning that not all contracts were viewed by someone with the necessary expertise to understand the Code and other requirements for such activities.

The Panel ruled breaches of the Code as acknowledged by Britannia including that Britannia had failed to maintain high standards in this regard. The Panel considered that Britannia had brought discredit upon, and reduced confidence in, the pharmaceutical industry and a breach of Clause 2 was ruled as acknowledged by Britannia.

2 Meetings alleged to be unapproved

The complainant noted that the PMCPA had previously dealt with a complaint regarding the senior Britannia leaders' trip to India in 2018 with two UK key opinion leaders. It was a complete surprise to the rest of the organisation, as the individuals mentioned had gone to a conference in Hong Kong (International Congress of Parkinson's Disease and Movement Disorders). The complainant stated that the Britannia leaders and the UK KOLs went on a promotional launch campaign, as evidenced by two YouTube videos.

The complainant stated that the meetings were not approved, although two UK health professionals were used to promote the use of Britannia's products. Britannia made promises of launching the products in India, and then decided not to.

The complainant stated that this behaviour was not acceptable (raising the hopes of patients and their carers) and cast a shadow on all of pharma. STADA (Britannia's parent company) ordered an internal investigation, but the report and findings were buried. The complainant was confident that the internal investigation report was not provided to the PMCPA.

The Panel noted that the documentation for the first health professional had been signed by him/her after the meetings had taken place but had not been signed by Britannia nor had it been provided in the company's response to Case AUTH/3302/1/20. It was not clear from Britannia's response in this case whether the second health professional had signed a contract. However, the company's response to Case AUTH/3302/1/20, which also referred to a meeting in India, included a signed contract with the second health professional which had been signed by the second health professional before the meetings and Britannia after the meetings. The Panel noted, however, that there was no specific allegation regarding the contracts for the two UK key opinion leaders. Whilst the approval of overseas meetings might include certification of the arrangements in relation to UK health professional speakers, it appeared to the Panel that the complainant's allegation was limited to the approval of the meetings themselves.

The Panel considered that with regard to certification of the meetings, the alleged promotion of the product in India to an Indian audience was not within the scope of the UK Code and therefore ruled no breach of the Code.

The Panel considered that it was most unfortunate that it appeared that Britannia had given health professionals and others in India the impression that the company would supply its product in India. The Panel noted Britannia's submission that the meetings were exploratory and the decision was taken not to proceed. The Panel, however, noted its comment above that the matter was not one within the scope of the UK Code and therefore ruled no breach of the Code in this regard.

The Panel noted its ruling that the meetings in India were not within the scope of the UK Code and considered that whilst it was important that companies provided full and frank responses to the Authority, on balance, in relation to the circumstances of this case, including that the complaint was not considered to be within the scope of the Code, failing to provide the information in relation to the report ordered by STADA and details of the contract with the second UK health professional was not a breach of the Code. The Panel thus ruled no breaches of the Code in this regard including Clause 2.

The parties were informed of the Panel's decision and the complainant appealed the Panel's out of scope of the UK Code ruling to an independent referee who decided to refer the matter back to the Panel for its consideration.

The complainant provided further comment.

The Panel noted that the 2016 Code would apply to this allegation as this was the relevant Code at the time of the meetings in question.

The Panel noted the principle of activities carried out by a UK company being covered by the ABPI Code, regardless of whether or not UK health professionals attended, only applied to activities in Europe as set out in the supplementary information. This requirement of the ABPI Code was from the EFPIA Code which was limited to activities which took place in Europe. A promotional meeting for French health professionals only, which took place in France and was organised by a UK company, would be potentially covered by the ABPI Code as a result of the implementation of the EFPIA Code requirement in the ABPI Code. There was no similar requirement for meetings held outside the UK but not in Europe. In such instances, whether the content of a meeting held outside the UK and not in Europe was subject to the ABPI Code would depend on whether UK delegates attended that meeting.

The Panel did not accept the complainant's view that the Code would apply conversely to the content of the meetings held in India for Indian delegates.

The Panel noted that two UK health professionals provided a service to Britannia and that service was clearly covered by the ABPI Code. The Panel considered, however, that the complaint was about the meetings and their content and not about the speakers and the arrangements in that regard as such.

The Panel noted that the Code required that meetings which involved travel outside the UK where a UK company funded UK delegates be certified. It also required that meetings involving travel outside the UK that were wholly or mainly for UK delegates must also be certified. The Panel noted that neither of these situations applied in this case.

The Panel considered that the allegation was in relation to the approval of the content of the meetings and not in relation to the approval of the arrangements for the speakers. As there were no UK delegates at the meetings, the company did not have to certify the content of the meetings. The Panel thus ruled no breach of the 2016 Code.

On the available information, it appeared from the two YouTube videos provided by the complainant that Britannia had given health professionals and others in India the impression that the company would supply its product in India. In one of the YouTube videos a Britannia employee stated that Britannia was working to move from a compassionate use

programme to full registration in the course of the following year. The Panel was concerned that health professionals and others might be disappointed about the decision not to launch the products in India. The Panel noted, however, Britannia's submission that it had visited a private hospital group in India to discuss named patient supply of apomorphine in 2018 and in early 2019, Britannia progressed a plan to supply named patient supply to the hospital group but during this time a local Indian company completed local registration of apomorphine for Parkinson's Disease. Britannia therefore decided not to proceed with named patient supply.

With regard to the content of the meetings, the Panel considered that on the available information they appeared to be promotional meetings for Indian health professionals in India. As the attendees were not UK health professionals, the Panel ruled no breach of the Code in relation to the allegation regarding the content of the meetings.

The Panel noted that there was no information before it about why senior Britannia leaders not informing the rest of the UK organisation about the meetings in India was in breach of the Code. Providing the relevant requirements of the Code were met, it was not, in itself, a breach of the Code for senior staff not to notify the rest of the UK organisation about its activities. In addition, the Panel noted its ruling above about the content of the meeting in India and therefore ruled no breach of the Code in relation to these allegations.

With regard to the complainant's concern that Britannia had not shared with the PMCPA the report of an internal investigation ordered by its parent company, STADA, the Panel noted Britannia's submission that Britannia had carried out a review of the supply opportunity and compliance requirements but concluded it was not possible to proceed because a local product was registered on the market. The Panel did not consider that Britannia's alleged failure to provide the PMCPA with a copy of a report in relation to the meeting in India would, in itself, be a breach of the Code. The Panel considered that the complainant had not discharged his/her burden of proof that not providing the report to the PMCPA was, on the balance of probabilities, a breach of the Code and ruled no breach of the Code in that regard. The Panel noted, however, that in Case AUTH/3302/1/20 Britannia submitted that a single UK health professional was present with the support of Britannia Pharmaceuticals at 3 hospital centres in India to evaluate the capability of these centres to prescribe its therapy and give an introductory lecture to the therapy. The Panel was concerned that Britannia had not referred to, or provided, the contract with the second UK health professional in its response to Case AUTH/3302/1/20. The Panel considered that Britannia's failure to refer to the contract with the second health professional in Case AUTH/3302/1/20 meant that it had failed to maintain high standards and a breach of the Code was ruled.

The Panel noted its rulings above about the content of the meetings in India and did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure reserved for such use and therefore ruled no breach of Clause 2.

3 Investigator led clinical trials

The complainant alleged that Britannia did not have proper standard operating procedures dealing with investigator-led clinical trials or non-interventional studies. Since 2015, health professionals who required funding would be given the necessary funds through medical and educational goods and services (MEGS). The marketing and medical teams at the time

did attempt to raise their concerns, but these were not taken seriously by the Britannia management committee.

The complainant stated that although he/she did not have access to company data, there were two trials (funded by Britannia), links to which were provided, that did not follow any procedures (as there were none at Britannia). The complainant stated that this was a small example of trials that were approved without due process. There was another clinical trial (proposed towards the end of 2018) funded by Britannia without any contracts or process before funds were paid.

The complainant further stated that he/she had realised that Britannia did not have appropriate SOPs to assess clinical trials or to ensure that patients were not harmed.

The Panel noted that the allegations referred to investigator-led trials and non-interventional studies. Britannia responded in relation to investigator-led trials supported by the company and that these were a mixture of interventional and non-interventional studies. The nine studies listed by Britannia appeared to have been funded by the company and carried out in the UK other than the one trial to be carried out in mainland Europe.

The Panel noted that Britannia could only locate electronic records for one of the two studies on the website identified by the complainant. The complainant had made a general allegation about the arrangements for studies.

The Panel noted Britannia's submission that it was clear from its investigation that in relation to investigator-led trials, Britannia had historically provided support and/or funding through the MEGS process which it now recognised was not appropriate.

The Panel was extremely concerned that Britannia had not considered patient safety when approving investigator-led trials; its pharmacovigilance colleagues were not engaged to address the safety aspect of the studies despite Britannia's submission that there were processes in place within the pharmacovigilance department.

The Panel noted Britannia's submission that in relation to the studies, the company failed to consider patient safety and to have the relevant approval processes in place. The Panel, therefore, ruled breaches of the Code including that high standards had not been maintained as acknowledged by Britannia.

The Panel considered that Britannia had brought discredit upon, and reduced confidence in, the pharmaceutical industry and ruled a breach of Clause 2 as acknowledged by Britannia.

The Panel noted Britannia's voluntary admission that these investigator-led clinical trials were not appropriately disclosed in breach of the Code was taken up in Case AUTH/3490/3/21.

Following its consideration of this case, the Panel decided that as Britannia's conduct, particularly in relation to Points 1 and 3 above raised concerns about the company's procedures, it warranted consideration by the Appeal Board. The Panel decided to report Britannia to the Appeal Board under Paragraph 8.2 of the Constitution and Procedure.

The Appeal Board noted that Britannia had provided brief details about its compliance plan and it had apologised for its failings.

The Appeal Board noted Britannia's submission that it had made a number of improvements and that the compliance structure had been strengthened over the last three years. The company was planning an external compliance audit in October 2021 to act as a benchmark to be repeated in a year.

The Appeal Board was extremely concerned about the multiple failings and Britannia's lack of control, checks and oversight that had led to the rulings in this case including two separate rulings of a breach of Clause 2. In accordance with Paragraph 11.3 of the Constitution and Procedure, the Appeal Board decided to require an audit of Britannia's procedures in relation to the Code. The audit should take place as soon as possible and those undertaking the audit should have access to the results of the external compliance audit. On receipt of the report of the audit, the Appeal Board would consider whether further sanctions were necessary.

At its meeting on 16 December 2021 the Appeal Board noted from the report of the November 2021 audit that Britannia was now working to develop a compliance framework and part of this was a move to an electronic system for the review of materials. It appeared that the staff did not have extensive experience in compliance and that the company decided to make changes following the complaints received by the PMCPA rather than recognising its short comings and acting upon them.

The Appeal Board noted Britannia's comments that it was deeply surprised that those carrying out the audit were concerned about an apparent lack of compliance framework, standard operating procedures (SOPs), training and guidance. The Appeal Board considered that this highlighted Britannia's lack of understanding of the seriousness of the situation. Britannia accepted that there were, historically, many failings in the organisation, these were described as people, process and culture failings. Much reliance appeared to be placed on a new member of staff. The Appeal Board was concerned that a senior member of staff was not providing sufficient leadership with regard to compliance and the audit and did not appear to be truly engaged in the process. The Appeal Board noted that there was no mention of the actions to be taken by the company in relation to the recommendations in the audit report. Britannia's comment that it had not committed to use an external provider to repeat a second review of materials a year after the first review was inconsistent with comments made by a senior Britannia employee at the Appeal Board meeting on 1 October 2021. At that meeting a slide headed 'Continuation of Compliance Plan 2021' and a time point 'Oct 2020 External Compliance Audit' were referred to by a senior Britannia employee who stated that 'We have invited an external audit partner to complete an external compliance audit on us which we are looking forward to seeing where we are, and we will use this as a benchmark and re-audit in a year or so to see if we've made improvements… '. The Appeal Board noted that Britannia had not provided the third party report when first requested and it had been necessary for the PMCPA to ask again for that material. In this regard the Appeal Board questioned Britannia's commitment to self regulation.

The Appeal Board asked the PMCPA to send Britannia a detailed response to the company's comments on the audit report.

The Appeal Board noted the number of concerns highlighted in recent cases and considered that there appeared to be a number of serious issues with the arrangements within Britannia which might impact on patient safety. The Appeal Board noted from the audit report that the

company had identified an error in the prescribing information which was described by some staff as a critical patient safety issue.

The Appeal Board noted that the audit report highlighted a number of other areas of concern including control of materials and activities, meetings and nurse activities.

The Appeal Board had grave concerns about the situation. It decided that in accordance with Paragraph 11.3 of the Constitution and Procedure, Britannia should be publicly reprimanded for its failure to have the necessary control of its activities with regard to compliance with the Code and its failure to provide a third party report when first requested. The Appeal Board also decided that Britannia should be re-audited. The Appeal Board decided that the re-audit should take place in six months' time at which point it expected the company to demonstrate significant progress. On receipt of the report for that re-audit the Appeal Board would decide whether further sanctions were necessary.

Given the exceptional circumstances of this matter, including the scale and seriousness of the difficulties at Britannia, the Appeal Board requested that certain senior employees should be invited to attend an Appeal Board meeting to discuss the Appeal Board's concerns. Prior to that meeting the company should provide its compliance action plan for addressing the issues identified in the audit report including a response to each of the recommendations.

At the Appeal Board meeting on 10 March 2022 Britannia submitted that it absolutely understood the seriousness of compliance and it was committed to making the relevant changes and improvements required. In its response it wanted to clearly demonstrate the improvements and changes it had made as an organisation thus far and commitment ongoing. Britannia submitted that the senior employee was fully involved and engaged in activities and correspondence with the PMCPA. Examples were given.

Britannia provided details of its compliance action plan following the PMCPA's recommendations in the report of the audit and provided details of the actions/mitigation steps. The Appeal Board noted that it had previously decided that Britannia should be re-audited in June/July 2022 and its expectation that Britannia demonstrate significant progress at the re-audit.

The Appeal Board noted the materials provided including the details in Britannia's compliance strategy for 2022.

One of the reasons the Appeal Board had publicly reprimanded Britannia was that it had not provided a copy of the third party report. In this regard Britannia explained that the reason for the delay was that it had been provided with a draft which it wanted to comment on before the third party finalised the report which would then be provided to the PMCPA.

The Appeal Board noted the second reason it had publicly reprimanded Britannia was for its failure to have the necessary control of its activities with regard to compliance with the Code. The Appeal Board was now encouraged that it appeared that Britannia had started to undertake compliance initiatives including job bag audits, a deviation process, a speak up speak out campaign, the appointment of compliance champions etc, and that the parent company was informed and investment had been made available for compliance resource.

The Appeal Board welcomed the progress that appeared to have been made so far. The Appeal Board still had concerns and requested that Britannia develop a governance framework going forward. The Appeal Board looked forward to the necessary improvements being demonstrated in the re-audit in June/July 2022 and did not consider that any further sanctions were required at this stage.

A complainant complained about arrangements at Britannia Pharmaceuticals UK in relation to a number of matters which were considered as follows.

1 Payments to Health Professionals

COMPLAINT

The complainant stated that over the last 4 years, Britannia had paid health professionals above the fair market value (FMV), not in keeping with its standard operating procedures (SOPs). The same speakers were used for promotional meetings, presenting almost identical slide sets. The complainant further stated that when compliance refused to sign-off on 'prep time', the speakers (under instruction from Britannia) added in a couple of slides or attended 'briefing meetings' (usually a quick phone call or discussion at the venue) to justify 'prep time' rates (average figure provided). This issue had been raised to senior management; however, no action was taken to stop this. In the complainant's view, it was fraudulent (breaching internal SOPs)/bribery (paying inflated fees to continue prescriptions/advocacy). At times, monies were paid to speakers even without contracts.

When writing to Britannia, the Authority asked it to consider the requirements of Clauses 2, 9.1, 18.1 and 23.1 (the latter in relation to fair market value, the alleged failure to have written contracts and the inducement provisions) of the Code.

RESPONSE

Britannia submitted that to enable it to provide a full and frank response it had undertaken an internal review of all payments made to health professionals for the period of 1 January 2017 until 1 January 2021. This review included all health professional payments made under consultancy (eg speaker meetings, advisory boards, promotional articles, etc). Payments made under individual sponsorship (ie congress attendance/registration fees) were not included. The review included examining the Britannia certification system, Veeva PromoMats, the Britannia purchase order system, Standard Assessment Procedure (SAP), and the Britannia Legal Contract Database for any Congress Symposiums, National and International speaker meetings, publications and other promotional activities.

Britannia stated that its response was based on the records that were electronically accessible, as its employees were working from home due to the ongoing Coronavirus pandemic. In total, it located over 200 payments made to health professionals for consultancy services over the period 1 January 2017 until 1 January 2021.

Britannia was committed to complying with the Code, and as such, health professional payments had been carefully compiled by using the fair market value (FMV) rates defined by the company. The pre-determined internal hourly rate within these SOPs and working instructions reflected the consultant's professional status and expertise. The FMV rates for all payments made in the timeframe mentioned above were provided. Having reviewed all payments, Britannia was confident

that the FMV rates were in keeping with its internal SOPs, and Britannia had found no evidence of inflated FMV rates being provided to health professionals.

If the activity required compliance and medical signatory oversight, the FMV rates were certified by way of a meeting approval form.

Britannia submitted that its internal review involved locating and checking all of the health professional contracts executed over the specified timeframe. Its Legal Department completed all *bone fide* health professional contracts. The contracts were requested by the meeting/activity initiator and were based on the initiator's information. Contracts that were created in 2017 appear to have been raised for a specific timeframe, and individual activities/engagements were not listed within the contract. As of 2018, Britannia's internal process changed, and health professional contracts had been raised for each engagement with a description of the engagement which could be found in schedule 1 of the contract. The full dataset was provided and Britannia provided a summary of its findings:

- 6% of contracts were not signed by one of the parties.
- 2.3% of contracts were signed after the activity had taken place.
- 30% of the contracts in question were not added to the electronic database. Britannia stated that once Covid restrictions allowed, it would check its hard copy files.

Britannia regretfully acknowledged that there were clear examples of payments having been made to health professionals without a fully executed contract in place.

Britannia stated that as of 2018, health professional contracts included a breakdown of the honorarium, including preparation time, briefing time and slide development, etc. In some instances, Britannia discovered a 'fixed fee' had been agreed, in which presentation time and preparation time had been combined. The preparation time varied dependent on the activity/engagement and materials requested by Britannia. Preparation time was included in the dataset provided to the Panel. It was evident that preparation time varied between 60 to 120 minutes on average.

However, there were examples of 240+ minute preparation time being granted for activities that required more time. To determine whether preparation time was being paid without justification, Britannia reviewed the slides for the 10 most frequently engaged health professionals for all of their engagements during the specified timeframe. The full dataset was provided.

A summary of Britannia's findings were provided:

- 30% of the slides were completely different, with a different topic and objectives.
- 50% had some similarities, but there were noticeable differences, including the addition of slides/data and changes to case studies etc. However, these differences did not warrant the preparation time that was paid for these engagements.
- 20% of the slides were identical, with the same objectives/titles and case studies. Regrettably, preparation time was paid for these engagements where it was not warranted nor required.

Britannia submitted that in its response to Case AUTH/3335/4/20, it accepted that there was one example whereby preparation time was paid to advisory board attendees; however, no pre-read was issued. Historically, health professionals were briefed by way of briefing calls and or in-person

ahead of the activity. There had been payments made for these briefing calls historically. Britannia acknowledged that this was not an ideal process, its would take the appropriate internal action to ensure that this process was rectified, and its internal SOPs required formalised briefing documents.

Britannia also conducted an internal review in relation to the complainant's allegation regarding using the same health professionals. Britannia reviewed the 10 health professionals who were most frequently engaged with Britannia on both global and UK-based projects. The full findings were provided. Of the engagements:

- 1 HCP was engaged 22 times (10%)
- 2 HCPs were engaged 8 times (3.8%)
- 1 HCP was engaged 7 times (2.3%)
- The other 6 HCPs were engaged >4 times (under 2%).

In summary, Britannia submitted that it was evident from the findings that there were failings internally regarding the contracting of health professionals and payments associated with preparation. Currently, the medical and compliance signatories did not have oversight of all health professional contracts. If the activity/engagement did not require a meeting approval form (MAF) (ie authorship for a publication), the contract/FMV rates were not viewed by the signatories.

Britannia acknowledged that this meant that not all health professional contracts would have been viewed by a subject matter expert or a member from medical affairs. Britannia committed to the Panel that it would update its SOP to ensure that a member of the compliance or medical affairs department reviewed all health professional contracts before being issued for signatures.

Britannia submitted that whilst its FMV rates were appropriate, Britannia acknowledged that in relation to implementation and calculation of the FMV rates regarding the preparation payments made to health professionals and contracting of health professionals, it was in breach of Clauses 2, 9.1, 18.1 and 23.1.

PANEL RULING

The Panel noted the requirements of Clause 23.1 of the 2019 Code in relation to the use of health professionals and other relevant decision makers as consultants and advisors, for services such as speaking at, and chairing, meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration and/or travel. The arrangements which cover these genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfil a number of criteria including, *inter alia*, that a written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services; the hiring of the consultant to provide the relevant service must not be an inducement to prescribe, supply, administer, recommend, buy or sell any medicine; and the compensation for the services must be reasonable and reflect the fair market value of the services provided. In this regard, token consultancy arrangements must not be used to justify compensating health professionals and other relevant decision makers.

The Panel noted that the supplementary information to Clause 18.1 stated that any payment to an individual for an activity that is ruled in breach of Clause 12.2 and/or Clause 23 is likely to be viewed as an unacceptable payment and thus in breach of Clause 18.1.

The Panel noted that Britannia's review of all health professional payments made under consultancy was based on the records that were electronically accessible; the company planned to check its hard copy files once Covid restrictions were lifted.

The Panel noted Britannia's submission that in relation to the complainant's allegation regarding using the same health professionals presenting almost identical slide sets, it had reviewed the arrangements from its electronic records for the 10 health professionals who were most frequently engaged with Britannia on both global and UK-based projects. Of the over 200 engagements, 1 health professional was engaged 22 times (10%), 2 health professionals were engaged 8 times (3.8%), 1 health professional was engaged 7 times (2.3%) and the other 6 health professionals were engaged >4 times (under 2%).

The Panel noted Britannia's submission that it found no evidence of inflated FMV rates being provided to health professionals and the FMV rates paid were in keeping with its internal SOPs using predetermined internal hourly rates which reflected the consultant's professional status and expertise. The Panel considered that the payment of the same amount of paid preparation time for when the same slides or essentially similar slides were used as that paid when a new presentation developed was unacceptable as the payment was not in relation to the work needing to be done. The Panel was very concerned that Britannia had made payments to health professionals for preparation time where it was not warranted nor required. In the Panel's view, the payments in these instances did not reflect the FMV of the services provided.

The Panel was further concerned to note Britannia's submission that there were also clear examples of payments having been made to health professionals without a fully executed contract in place. It was very concerning that not all health professional contracts were viewed by medical and compliance signatories or someone with the necessary expertise to understand the Code and other requirements for such activities.

The Panel noted that the requirements in Clause 23.1 were the same in the 2016 and 2019 Codes and that the differences between Clause 18.1 in the 2016 and 2019 Codes were in relation to supplementary information for package deals and was not relevant to the allegations under consideration in this case. Clauses 2 and 9.1 were the same in the two codes. The Panel therefore decided to use the 2019 Code. The Panel ruled a breach of Clause 23.1 of the 2019 Code and also ruled a breach of Clause 18.1 as acknowledged by Britannia.

The Panel considered that Britannia had failed to maintain high standards in this regard and ruled a breach of Clause 9.1 as acknowledged by Britannia.

The Panel noted that examples of activities that were likely to be in breach of Clause 2 included unacceptable payments. The Panel noted its rulings and comments above and considered that Britannia had thus brought discredit upon, and reduced confidence in, the pharmaceutical industry and a breach of Clause 2 was ruled as acknowledged by Britannia.

2 Meetings alleged to be unapproved

COMPLAINT

The complainant noted that the PMCPA had previously dealt with a complaint regarding a senior employee's trip to India in 2018. The complainant stated that senior Britannia leaders, went to India with two UK key opinion leaders (KOLs). It was a complete surprise to the rest of the organisation, as the individuals mentioned went to a conference in Hong Kong (International Congress of

Parkinson's Disease and Movement Disorders). The complainant stated that the Britannia leaders and the UK KOLs went on a promotional launch campaign, as evidenced by two YouTube videos, links to which were provided.

The complainant stated that the meetings were not approved, although two UK health professionals were used to promote the use of Britannia's products. Britannia made promises of launching the products in India, and then decided not to.

The complainant stated that this behaviour was not acceptable (raising the hopes of patients and their carers) and cast a shadow on all of pharma. STADA (Britannia's parent company) ordered an internal investigation, but the report and findings were buried. The complainant was confident that the internal investigation report was not shared with the PMCPA as part of Britannia's response.

When writing to Britannia, the Authority asked it to consider the requirements of Clauses 2, 9.1 and 14.2 with regard to activities in relation to overseas meetings and Clauses 9.1 and 2 in relation to its response in Case AUTH/3302/1/20.

RESPONSE

Britannia submitted that as stated previously, the overseas meetings were exploratory. The decision was taken not to proceed; no Britannia products nor devices were shipped to the hospital group, nor had Britannia ever shipped any product to India.

Britannia stated that it previously confirmed that one UK health professional was present with Britannia's support at three hospital centres in India to evaluate those centres' capability to prescribe Britannia's therapy and give an introductory lecture to it. Britannia located a signed contract for the second health professional in attendance, but unfortunately it was not signed by Britannia.

PANEL RULING

The Panel noted that the documentation for one of the health professionals provided in Britannia's response to this case stated that the services would take place in December 2018 and had been signed by the health professional after the week of the meetings but had not been signed by Britannia nor had it been provided in the company's response to Case AUTH/3302/1/20. It was not clear whether this contract was one of those referred to in Point 1 above. It was not clear from Britannia's response in this case whether the second health professional had signed a contract. However, the company's response to Case AUTH/3302/1/20, which also referred to a meeting in India, included a signed contract with the second health professional which covered some of the same services as the contract with the first health professional which had been signed by the second health professional ahead of the week of the meetings and by Britannia after the week of the meetings. The Panel noted, however, that there was no specific allegation regarding the contracts for the two UK key opinion leaders. The Panel noted that whilst the approval of overseas meetings might include certification of the arrangements in relation to UK health professional speakers, it appeared to the Panel that the complainant's allegation was limited to the approval of the meetings themselves.

The Panel considered that with regard to certification of the meetings, the events in India regarding the alleged promotion of the product in India to an Indian audience was not within the scope of the UK Code. The principle of activities carried out by a UK company being covered by the UK Code, regardless of whether or not UK health professionals attended, only applied to activities in Europe

as set out in the supplementary information to Clause 1.11. The Panel therefore ruled no breach of Clauses 14.2, 9.1 and 2.

The Panel considered that it was most unfortunate that it appeared from the two YouTube videos provided by the complainant that Britannia had given health professionals and others in India the impression that the company would supply its product in India. The Panel noted Britannia's submission that the meetings were exploratory and the decision was taken not to proceed. The Panel, however, noted its comment above that the matter was not one within the scope of the UK Code. The Panel therefore ruled no breach of the Code in this regard.

The Panel noted the complainant's concern that Britannia had not shared with the PMCPA the report and findings of an internal investigation ordered by its parent company, STADA. The Panel noted that Britannia had made no submission in this regard.

The Panel was concerned that Britannia had not referred to the contract with the second UK health professional in its response to Case AUTH/3302/1/20. It was not clear to the Panel if Britannia was aware of the YouTube videos submitted by the complainant in this case when it had responded in relation to Case AUTH/3302/1/20; Britannia had made no comments with regard to the YouTube videos in its response to this case. There was no allegation that the YouTube videos had not been provided.

The Panel noted its ruling that the meetings in India were not within the scope of the UK Code and considered that whilst it was important that companies provided full and frank responses to the Authority, on balance, in relation to the circumstances of this case, including that the complaint was not considered to be within the scope of the Code, failing to provide the information was not a breach of the Code. The Panel thus ruled no breach of Clauses 9.1 and 2 in this regard.

* * * * *

The parties were informed of the Panel's decision and the complainant appealed the Panel's out of scope of the UK Code ruling to an independent referee who decided to refer the matter back to the Panel for its consideration.

FURTHER INFORMATION FROM THE COMPLAINANT

The complainant appealed against the ruling of no breach of the Code as the meetings in India were not within the scope of the Code. The complainant would demonstrate that the India meetings fell within the scope of the Code.

The complainant stated that the Panel had a different view/interpretation of his/her initial complaint. The meetings in India were not approved, meaning that the meetings were not certified/checked by compliance/medical.

The meetings in India took place without the knowledge of most individuals in the company. senior Britannia staff travelled to Hong Kong for the International Congress of Parkinson's Disease and Movement Disorders Conference. It then transpired that some Britannia employees, along with the 2 UK-based clinicians diverted to India to do a series of promotional meetings in private hospitals, and not exploratory meetings as suggested by Britannia (two YouTube videos evidenced this).

In the complainant's view, the case fell within the scope of the Code for the following reasons:

- a UK-based pharmaceutical company, with UK-based employees arranged unapproved/uncertified/unchecked meetings in India using two UK-based health professionals

- the WHO (World Health Organisation) criteria and the 2016 Code.

The complainant stated that the WHO Ethical Criteria for Medicinal Drug Promotion (as referenced by the Code of Practice) stated that the main objective of ethical criteria for medicinal drug promotion was to support and encourage the improvement of healthcare through the rational use of medicinal drugs. It further described Ethical Criteria – the interpretation of what was ethical varied in different parts of the world and in different societies. The issue in all societies was what was proper behaviour. Ethical criteria for drug promotion should lay the foundation for proper behaviour concerning the promotion of medicinal drugs, consistent with the search for truthfulness and righteousness.

The criteria should thus assist in judging if promotional practices related to medicinal drugs were in keeping with accepted ethical standards.

If STADA (Britannia's parent company) initiated an investigation that eventually led to the dismissal of employees, it was evident that improper business practices took place.

The complainant referred to various clauses of the 2016 ABPI Code as follows:

1 Section 1.11 Applicability of Codes (2016 Code)

> 'Activities carried out and materials used in a European country by a pharmaceutical company located in a country other than a European country must comply with the EFPIA [European Federation of Pharmaceutical Industries and Associations] Code as well as the national code of the country in which the activities are carried out and materials are used.'
>
> 'All international events, that is to say events that take place outside the responsible pharmaceutical company's home country, must be notified in advance to any relevant local subsidiary or local advice taken.'

The complainant stated that the above demonstrated the relationship and the expectations that the EFPIA Code had with pharmaceutical companies that were based outside of Europe. That rule would therefore apply conversely. If a European-based company was carrying out activities outside of a European country, activities and materials must comply with the EFPIA Code and the national code in which the activities are carried out, and material are used.

There was no specific or definitive advice that the Code does not apply to activities outside of Europe under Clause 1.11. In fact, the Clauses of the Code reference to meetings held outside of the UK, which, if one inter-operates, involves meetings outside of the UK, be it in Europe or further afield.

2 Clause 14.2

> 'All meetings involving travel outside the UK where a UK company funds UK delegates must be certified in advance in a manner similar to that provided for by Clause 14.1.'

Clause 14.2 Meetings Involving Travel Outside the U K (Supplementary Information):

> 'UK Companies have responsibilities under the Code for meetings which they organise and when UK delegates and/or UK speakers are invited or supported to go to meetings outside the UK. Clauses 23 and 24 in relation to disclosure of transfers of value will also need to be followed.'
>
> 'When certifying arrangements for meetings which involve travel outside the UK all the relevant documents and arrangements must be considered including the programme, the venue, the reasons for using that venue, the intended audience, the anticipated cost and the nature of the hospitality and the like.'

Clause 14.2 Presentations by UK Speakers at Meetings Held Outside the UK (Supplementary Information):

> 'When a pharmaceutical company based outside the UK arranges via a UK company for a UK speaker to present at a meeting to be held outside the UK, then that speaker's presentation materials do not need to be certified or examined by the UK provided there are no UK delegates and the UK company has no role whatsoever in relation to the meeting or the presentation. In such circumstances the meeting arrangements, in as much as they apply to the UK speaker, will not have to be certified or examined.'

The complainant stated it was clear from the referenced sections that all meetings that involved travel outside the UK should have some form of checks/certification, especially when a UK-based company had a role. If the Code only applied to European countries, the wording would state that all meetings within Europe. Britannia had already confirmed it had arranged meetings in India with two UK health professionals.

3 Clause 22.1 Meetings and Hospitality, Supplementary Information

> 'Promotional material which is displayed or provided at international meetings held outside the UK may, unless prohibited or otherwise regulated by local laws and regulations, refer to medicines or their indications which are not registered in the country where the event takes place, or which are registered under different conditions, so long as any such material is accompanied by a suitable statement indicating countries where the product is registered and making clear that the product is not registered locally. Any such promotional material which refers to the prescribing information authorized in a country or countries where the medicine is registered must be accompanied by an explanatory statement indicating that registration conditions differ internationally.'
>
> 'Pharmaceutical companies must ensure that all meetings which are planned are checked to see that they comply with the Code. Companies must have a written document that sets out their policies on meetings and hospitality and the associated allowable expenditure. In addition, meetings which involve travel outside the UK must be formally certified as set out in Clause 14.2.'

The complainant stated that the Code was clear in its expectations that all meetings should be checked to ensure compliance with the Code.

Summary

The complainant stated that even as the India meetings were the subject of a PMCPA complaint, Britannia did not provide full disclosure by stating that only one UK health professional was initially contracted and that the meetings were exploratory. Britannia and its parent company STADA would like this matter closed, as it demonstrated a systematic failure of compliance control. STADA initiated an internal investigation, yet the report was not provided to the Panel. The impression of impropriety with not being transparent or providing the Panel with all the necessary facts was very concerning.

The complainant referred to medics always referencing the 'Daily Mail test' – all activities should have appropriate justification and checks to avoid embarrassment. If this issue were public knowledge, the press would have a field day.

The complainant stated that if this precedent was made, certain pharmaceutical companies that were based in the EU might think that the Code/EFPIA did not apply outside of Europe in any situation. Therefore, compliance/medical would not need to check meeting arrangements, review material, consultant fees, or contracts if the meetings occur outside of Europe, leading to a lack of control.

FURTHER RESPONSE FROM BRITANNIA

Context of the meetings

Britannia explained that as previously stated in its response to Case AUTH/3302/1/20, Britannia employees visited a hospital group in India in 2018 to discuss named patient supply. In early 2019, Britannia progressed a plan to supply named patient supply to the hospital group; during this time, a local Indian Company, completed local registration of Apomorphine for Parkinson's Disease.

Britannia confirmed that no product or devices were shipped to the hospital group in India, nor had Britannia ever shipped any product to India. Regarding the allegations that Britannia was instructed to carry out an internal investigation, Britannia carried out a review of the supply opportunity and compliance requirements but concluded it was not possible to proceed because a local product was registered on the market.

The meetings were not formally certified or examined by compliance nor medical, however, as per the above, a contracted member of the medical department was aware of the meetings and was involved in the decision to not proceed with the named patient supply.

Disclosure to the PMCPA

Britannia stated it was committed to transparency and had disclosed all necessary facts to the Panel along with the details and associated contracts of both the UK health professionals in attendance at these meetings.

In response to Case AUTH/3302/1/20, Britannia stated that it confirmed that a UK health professional was present with the support of Britannia to evaluate the capabilities of three hospitals to prescribe Britannia's therapy and to give an introductory lecture. Britannia submitted that the honorarium provided, agenda for the UK health professional and their contract of services, was in its response.

Britannia stated that its response to Case AUTH/3355/5/20, confirmed that it had managed to locate the second UK health professional contract. This contract was located during an internal review of all health professional payments and contracts which was initiated to enable Britannia to respond to Case AUTH/3355/5/20.

Further response from the complainant

The complainant noted that Britannia had not contested that the India meetings were out of the scope of the Code.

The complainant stated that the meetings in India were promotional launch meetings as evidenced by the two YouTube videos referenced in the original complaint.

The complainant referred to STADA, Britannia's parent company, investigation following the India meetings in previous correspondence. As a result of this investigation, senior leaders in Britannia were removed from the business.

The complainant also noted that Britannia had not disclosed all of the health professional payments in its original response to Case AUTH/3302/1/20 but located the second health professional contract in February 2021 in response to this case, Case AUTH/3355/5/20.

The complainant stated that, in his/her view, the case fell within the scope of the Code for the following reasons:

1 A UK-based pharmaceutical company, with UK-based employees arranged unapproved/uncertified/unchecked meetings in India using two UK-based health professionals.

2 Britannia had admitted that the meetings were not formally certified or examined by Compliance nor Medical.

3 A UK-based pharmaceutical company contracted two UK-based health professionals to carry out advisory boards, which were promotional meetings in India (as evidenced by the two YouTube videos).

4 The Managing Director for a UK-based company with UK-based health professionals (contracted by a UK-based pharmaceutical company) promoted medicine directly to health professionals and non-health professionals, as demonstrated in the YouTube video.

5 The WHO criteria and the 2016 Code.

PANEL RULING

The Panel noted that the 2016 Code would apply to this allegation as this was the relevant Code at the time of the meetings in question.

The Panel noted the complainant's comments about the WHO Ethical Criteria. The Panel's role was to consider complaints under the ABPI Code which incorporated the principles set out in the

World Health Organisation's Ethical Criteria for Medicinal Drug Promotion. It could not consider cases under the WHO Ethical Criteria.

The Panel noted the principle of activities carried out by a UK company being covered by the ABPI Code, regardless of whether or not UK health professionals attended, only applied to activities in Europe as set out in the supplementary information to Clause 1.11. This requirement of the ABPI Code was from the EFPIA Code which was limited to activities which took place in Europe. A promotional meeting for French health professionals only, which took place in France and was organised by a UK company, would be potentially covered by the ABPI Code as a result of the implementation of the EFPIA Code requirement in the ABPI Code. There was no similar requirement for meetings held outside the UK but not in Europe. In such instances, whether the content of a meeting held outside the UK and not in Europe was subject to the ABPI Code would depend on whether UK delegates attended that meeting.

The Panel did not accept the complainant's view that Clause 1.11 would apply conversely to the content of the meetings held in India for Indian delegates.

The Panel noted that two UK health professionals provided a service to Britannia and that service was clearly covered by the ABPI Code. The Panel considered, however, that the complaint was about the meetings and their content and not about the speakers and the arrangements in that regard as such.

The Panel noted that Clause 14.2 of the 2016 Code required that meetings which involved travel outside the UK where a UK company funded UK delegates must be certified. It also required that meetings involving travel outside the UK that were wholly or mainly for UK delegates must also be certified. The Panel noted that neither of these situations applied in this case.

The supplementary information to Clause 14.2 Meetings Involving Travel Outside the UK included that companies had responsibilities under the Code for meetings which they organised and when UK delegates and/or UK speakers were invited or supported to attend meetings outside the UK. The supplementary information referred to the requirements for disclosing transfers of value and the factors to consider when certifying the arrangements for meetings which involved travel outside the UK.

The Panel noted that were no UK delegates at the meeting. The delegates were from India. The speakers were from the UK, including senior staff at Britannia. Britannia acknowledged that the arrangements were not certified. The Panel considered that the allegation was in relation to the approval of the content of the meetings and not in relation to the approval of the arrangements for the speakers. As there were no UK delegates at the meetings, the company did not have to certify the content of the meetings. The Panel thus ruled no breach of Clause 14.2 of the 2016 Code.

On the available information, it appeared from the two YouTube videos provided by the complainant that Britannia had given health professionals and others in India the impression that the company would supply its product in India. In one of the YouTube videos a Britannia employee stated that Britannia was working to move from a compassionate use programme to full registration in the course of the following year. The Panel was concerned that health professionals and others might be disappointed about the decision not to launch the products in India. The Panel noted, however, Britannia's submission that it had visited a hospital group in India to discuss named patient supply of apomorphine in 2018 and in early 2019, Britannia progressed a plan to supply named patient supply to the hospital group but during this time a local Indian company completed local registration of

apomorphine for Parkinson's Disease. Britannia therefore decided not to proceed with named patient supply because the product was registered and therefore no import was required.

With regard to the content of the meetings, the Panel considered that on the available information they appeared to be promotional meetings for Indian health professionals in India. As the attendees were not UK health professionals, the Panel ruled no breach of Clause 9.1 of the Code in relation to the allegation regarding the content of the meetings.

The Panel noted that there was no information before it about why Britannia's senior leaders not informing the rest of the UK organisation about the meetings in India was alleged to be in breach of the Code. Providing the activities and materials met the relevant requirements of the Code, it was not, in itself, a breach of the Code for senior staff not to notify the rest of the UK organisation about its activities. In addition, the Panel noted its ruling above about the content of the meeting in India and therefore ruled no breach of Clause 9.1 of the Code in relation to these allegations.

With regard to the complainant's concern that Britannia had not shared with the PMCPA the report and findings of an internal investigation ordered by its parent company, STADA, the Panel noted Britannia's submission that Britannia had carried out a review of the supply opportunity and compliance requirements but concluded it was not possible to proceed because a local product was registered on the market. Neither the complainant nor the respondent provided a copy of the investigation report. The Panel noted that the case preparation manager had referred to Case AUTH/3302/1/20 when advising Britannia of this complaint (Case AUTH/3355/5/20) and asked it to respond in relation to the completeness of its response in that case including in relation to the provision of the report referred to above. The Panel noted that it was important that companies provided full and frank responses to the PMCPA, failing to provide information was very likely to mean that a company had not maintained high standards and had brought discredit upon, and reduced confidence in, the pharmaceutical industry. The Panel did not consider that Britannia's alleged failure to provide the PMCPA with a copy of a report in relation to the meeting in India would, in itself, be a breach of the Code. The Panel considered that the complainant had not discharged his/her burden of proof that not providing the report to the PMCPA was, on the balance of probabilities, a breach of the Code and no breach of Clause 9.1 was ruled in that regard. The Panel noted, however, that in Case AUTH/3302/1/20 Britannia submitted that a single UK health professional was present with the support of Britannia Pharmaceuticals at 3 hospital centres in India to evaluate the capability of these centres to prescribe its therapy and give an introductory lecture to the therapy. The Panel was concerned that Britannia had not referred to, or provided, the contract with the second UK health professional in its response to Case AUTH/3302/1/20. It was not clear to the Panel if Britannia was aware of the YouTube videos submitted by the complainant in Case AUTH/3355/5/20 when it had responded in relation to Case AUTH/3302/1/20; Britannia had made no comments with regard to the YouTube videos in its response to this case. The Panel considered that Britannia's failure to refer to the contract with the second health professional in Case AUTH/3302/1/20 meant that it had failed to maintain high standards and a breach of Clause 9.1 was ruled.

The Panel noted its rulings above about the content of the meetings in India and did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure reserved for such use and therefore ruled no breach of Clause 2 of the Code.

3 Investigator led clinical trials

COMPLAINT

The complainant alleged that Britannia did not have proper standard operating procedures dealing with investigator-led clinical trials or non-interventional studies. Since 2015, health professionals who required funding would be given the necessary funds through medical and educational goods and services (MEGS). The marketing and medical teams at the time did attempt to raise their concerns, but these were not taken seriously by the Britannia management committee.

The complainant stated that although he/she did not have access to company data, there were two trials (funded by Britannia), links to which were provided, on a third party website that did not follow any procedures (as there were none at Britannia). The complainant stated that this was a small example of trials that were approved without due process. There was another clinical trial (proposed towards the end of 2018) run in mainland Europe that was funded by Britannia without any contracts or process before funds were paid.

The complainant further stated that he/she had realised that Britannia did not have appropriate SOPs to assess clinical trials or to ensure that patients were not harmed.

When writing to Britannia, the Authority asked it to consider the requirements of Clauses 2, 9.1, 13.4 and 25.2 of the Code.

RESPONSE

Britannia stated that it had several clinical SOPs in force until 2018; these were created and administered by the Phase 2 and Phase 3 Clinical Trials Team. When these individuals left the business in 2018, their duties were absorbed by other research and development team members and the SOPs were made obsolete. The rationale behind making these SOPs obsolete was undocumented. Copies of the SOPs were provided. Britannia submitted that it had undertaken an internal review of all investigator-led trials (interventional and non-interventional) funded by the company and provided details.

Britannia noted that the complainant identified two studies and Britannia located the paperwork for one of the studies . Based on its findings, Britannia submitted that a MEGS was provided to fund fellows to oversee the studies. Britannia submitted that it had no electronic records relating to the other study. Britannia provided funding to a mainland Europe disease association for a study which was yet to commence. The grant was paid in 2019, and the MEGS contract was provided in 2020; however, it was yet to be signed.

Britannia submitted that it was clear from the findings that in relation to investigator-led trials, Britannia had historically provided support and/or funding through the medical and educational goods and services (MEGS) process. It now recognised that this was not the appropriate approval process for investigator-led trials.

Britannia's pharmacovigilance colleagues were not engaged to address the safety aspect of the studies despite there being processes in place within the pharmacovigilance department. Britannia submitted that it did not consider patient safety when approving these investigator-led trials.

Britannia acknowledged, in relation to the clinical studies, that by failing to consider patient safety and have the relevant approval processes in place, it had breached Clauses 2, 9.1, 13.4 and 25.2. Britannia committed to the Panel to ensure that the appropriate procedures were put in place before further studies were considered for funding. Britannia also acknowledged that these investigator-led

trials were not appropriately disclosed to the ABPI and therefore voluntarily admitted to having breached Clauses 13.3 and 13.1.

PANEL RULING

The Panel noted that the allegations referred to investigator-led trials and non-interventional studies. Britannia responded in relation to investigator-led trials supported by the company and that these were a mixture of interventional and non-interventional studies. The nine studies listed by Britannia appeared to have been funded by the company and carried out in the UK other than the one trial to be carried out in mainland Europe.

The Panel noted that Clause 25.2 required companies to have a scientific service to deal with the approval and supervision of non-interventional studies. This scientific service must include a registered medical practitioner or a pharmacist registered in the UK, who would be responsible for the oversight of non-interventional studies (including the review of any responsibilities relating to such studies, particularly those given to medical representatives). That person must state in writing that he or she has examined the protocol relating to the non-interventional study and that, in his or her belief, it is in accordance with the requirements of the Code. The clause did not distinguish between studies run by the company and those which were run by investigators with funding or other input from the pharmaceutical company.

The Panel noted Britannia's submission that it had several clinical trial SOPs in force until 2018, however, they were made obsolete when individuals in the Phase 2 and Phase 3 Clinical Trials Team who created and administered them left the business in 2018 and their duties were absorbed by other Research and Development team members.

The Panel noted that Britannia could only locate electronic records for one of the two studies on the third party website identified by the complainant. The complainant had made a general allegation about the arrangements for studies.

The Panel noted Britannia's submission that it was clear from its investigation that in relation to investigator-led trials, Britannia had historically provided support and/or funding through the MEGS process which it now recognised was not appropriate.

The Panel was extremely concerned that Britannia had not considered patient safety when approving investigator-led trials; its pharmacovigilance colleagues were not engaged to address the safety aspect of the studies despite Britannia's submission that there were processes in place within the pharmacovigilance department.

The Panel noted that the requirements in Clauses 13 and 25 were the same in the 2016 and 2019 Codes. Clauses 2 and 9.1 were also the same in the two codes. The Panel, therefore, decided to use the 2019 Code. The Panel noted Britannia's submission that in relation to the studies, the company failed to consider patient safety and to have the relevant approval processes in place. The Panel, therefore, ruled a breach of Clauses 13.4 and 25.2 as acknowledged by Britannia.

The Panel considered that the company had failed to maintain high standards in this regard and ruled a breach of Clause 9.1 as acknowledged by Britannia.

The Panel noted that examples of activities that were likely to be in breach of Clause 2 included, *inter alia*, prejudicing patient safety and/or public health, unacceptable payments and conduct of company employees/agents that fell short of competent care. The Panel noted its rulings and

comments above and considered that Britannia had thus brought discredit upon, and reduced confidence in, the pharmaceutical industry and a breach of Clause 2 was ruled as acknowledged by Britannia.

The Panel noted Britannia's voluntary admission that these investigator-led clinical trials were not appropriately disclosed to the ABPI in breach of Clauses 13.3 and 13.1 which was taken up in Case AUTH/3490/3/21.

Following its consideration of this case, the Panel decided that as Britannia's conduct, particularly in relation to Points 1 and 3 above raised concerns about the company's procedures, it warranted consideration by the Appeal Board. The Panel decided to report Britannia to the Appeal Board under Paragraph 8.2 of the Constitution and Procedure.

COMMENTS FROM BRITANNIA ON THE REPORT

Britannia accepted the breaches of the Code ruled by the Panel and it stated that it understood the gravity of such rulings.

* * * * *

At the consideration of the report, Britannia acknowledged its failings in processes and governance. The company referred to its failure to have the relevant approval procedures in place with regard to clinical trials and not considering patient safety. Britannia apologised for failing to meet its obligations to the Code.

Britannia stated it had implemented its SOPs in the calculation of the FMV rates on the preparation of payments and contracting of health professionals.

Britannia submitted that to embed a strong compliance culture it had created a medical affairs department, moved to a more open communication of compliance management, it was creating a compliance strategy and it had hired two permanent compliance officers. Britannia submitted that it operated with:

- Integrity - Each and every one acted ethically in line with the company's internal and external standards. Actions were led by speaking up and respect.

- Entrepreneurship - Each and every one drove new ideas and actions, creating future growth and value.

- Agility – Each and every one led change with flexibility and decisiveness as part of an ongoing journey of personal development. One Strada - Each and every one acted in the best interests of the company as a whole rather than as a business unit or function in order to build one successful STADA.

Britannia gave details of its compliance plan for 2020 and 2021 including completed and planned activities including that a job bag compliance spot check had taken place in August 2021 and an external compliance audit was due in October 2021. This would be a benchmark and would be repeated a year later.

Britannia acknowledged that there were gaps within its internal processes and apologised for these failings. Compliance was one of the fundamental pillars of the business. Britannia submitted that it was committed to addressing its people, culture and processes.

APPEAL BOARD CONSIDERATION OF THE REPORT FROM THE PANEL

The Appeal Board noted the Panel's comments and rulings of breaches of Clauses 2, 9.1, 13.4, 18.1, 23.1 and 25.2 of the Code including its decision to report Britannia to the Appeal Board. The Appeal Board noted that Britannia had provided brief details about its compliance plan and it had apologised for its failings.

The Appeal Board noted Britannia's submission that it had made a number of improvements including moving to an electronic system, training, additional compliance resource and updated processes to address the issues highlighted by this case. The company submitted that the compliance structure had been strengthened over the last three years. Britannia stated that it was planning an external compliance audit in October 2021 to act as a benchmark to be repeated in a year.

The Appeal Board was extremely concerned about the multiple failings and Britannia's lack of control, checks and oversight that had led to the rulings in this case including two separate rulings of a breach of Clause 2. In accordance with Paragraph 11.3 of the Constitution and Procedure, the Appeal Board decided to require an audit of Britannia's procedures in relation to the Code. The audit should take place as soon as possible and those undertaking the audit should have access to the results of the external compliance audit. On receipt of the report of the audit, the Appeal Board would consider whether further sanctions were necessary.

APPEAL BOARD FURTHER CONSIDERATION

At its meeting on 16 December 2021 the Appeal Board noted from the report of the November 2021 audit that Britannia was now working to develop a compliance framework and part of this was a move to an electronic system for the review of materials. It appeared that the staff did not have extensive experience in compliance and that the company decided to make changes following the complaints received by the PMCPA rather than recognising its short comings and acting upon them.

The Appeal Board noted Britannia's comments that it was deeply surprised that those carrying out the audit were concerned about an apparent lack of compliance framework, standard operating procedures (SOPs), training and guidance. The Appeal Board considered that this highlighted Britannia's lack of understanding of the seriousness of the situation. Britannia accepted that there were, historically, many failings in the organisation, these were described as people, process and culture failings. Much reliance appeared to be placed on a new member of staff. The Appeal Board was concerned that a senior member of staff was not providing sufficient leadership with regard to compliance and the audit and did not appear to be truly engaged in the process. The Appeal Board noted that there was no mention of the actions to be taken by the company in relation to the recommendations in the audit report. Britannia's comment that it had not committed to use an external provider to repeat a second review of materials a year after the first review was inconsistent with comments made by a senior Britannia employee at the Appeal Board meeting on 1 October 2021. At that meeting a slide headed 'Continuation of Compliance Plan 2021' and a time point 'Oct 2020 External Compliance Audit' were referred to by a senior Britannia employee who stated that 'We have invited an external audit partner to complete an external compliance audit on us which we are looking forward to seeing where we are, and we will use this as a benchmark and re-audit in a year or so to see if we've made improvements… '. The Appeal Board noted that Britannia had not

provided the third party report when first requested and it had been necessary for the PMCPA to ask again for that material. In this regard the Appeal Board questioned Britannia's commitment to self regulation.

The Appeal Board asked the PMCPA to send Britannia a detailed response to the company's comments on the audit report.

The Appeal Board noted the number of concerns highlighted in recent cases and considered that there appeared to be a number of serious issues with the arrangements within Britannia which might impact on patient safety. The Appeal Board noted from the audit report that the company had identified an error in the prescribing information which was described by some staff as a critical patient safety issue.

The Appeal Board noted that the audit report highlighted a number of other areas of concern including control of materials and activities, meetings and nurse activities.

The Appeal Board had grave concerns about the situation. It decided that in accordance with Paragraph 11.3 of the Constitution and Procedure, Britannia should be publicly reprimanded for its failure to have the necessary control of its activities with regard to compliance with the Code and its failure to provide a third party report when first requested. The Appeal Board also decided that Britannia should be re-audited. The Appeal Board decided that the re-audit should take place in six months' time at which point it expected the company to demonstrate significant progress. On receipt of the report for that re-audit the Appeal Board would decide whether further sanctions were necessary.

Given the exceptional circumstances of this matter, including the scale and seriousness of the difficulties at Britannia, the Appeal Board requested that certain senior employees should be invited to attend an Appeal Board meeting to discuss the Appeal Board's concerns. Prior to that meeting the company should provide its compliance action plan for addressing the issues identified in the audit report including a response to each of the recommendations.

APPEAL BOARD FURTHER CONSIDERATION

At the Appeal Board meeting on 10 March 2022 Britannia submitted that it absolutely understood the seriousness of compliance and it was committed to making the relevant changes and improvements required. In its response it wanted to clearly demonstrate the improvements and changes it had made as an organisation thus far and commitment ongoing. Britannia submitted that the senior employee was fully involved and engaged in activities and correspondence with the PMCPA. Examples were given.

Britannia provided details of its compliance action plan following the PMCPA's recommendations in the report of the audit and provided details of the actions/mitigation steps. The Appeal Board noted that it had previously decided that Britannia should be re-audited in June/July 2022 and its expectation that Britannia demonstrate significant progress at the re-audit.

The Appeal Board noted the materials provided including the details in Britannia's compliance strategy for 2022.

One of the reasons the Appeal Board had publicly reprimanded Britannia was that it had not provided a copy of the third party report. In this regard Britannia explained that the reason for the

delay was that it had been provided with a draft which it wanted to comment on before the third party finalised the report which would then be provided to the PMCPA.

The Appeal Board noted the second reason it had publicly reprimanded Britannia was for its failure to have the necessary control of its activities with regard to compliance with the Code. The Appeal Board was now encouraged that it appeared that Britannia had started to undertake compliance initiatives including job bag audits, a deviation process, a speak up speak out campaign, the appointment of compliance champions etc, and that the parent company was informed and investment had been made available for compliance resource.

The Appeal Board welcomed the progress that appeared to have been made so far. The Appeal Board still had concerns and requested that Britannia develop a governance framework going forward. The Appeal Board looked forward to the necessary improvements being demonstrated in the re-audit in June/July 2022 and did not consider that any further sanctions were required at this stage.

Complaint received	**22 May 2020**
Undertaking received	**7 September**
Appeal Board consideration	**1 October 2021, 16 December, 10 March 2022**
Interim case report first published	**24 February 2022**