

**CASE AUTH/2780/7/15**

## **ANONYMOUS, NON-CONTACTABLE EMPLOYEE v ASTELLAS**

### **False response and further failure to provide accurate information**

**An anonymous and non-contactable complainant who appeared to be an employee of Astellas complained about the truthfulness of Astellas's response to Case AUTH/2747/1/15 which concerned the arrangements for an Astellas Pharma Europe meeting held in Milan in February 2014. In that case the company was ruled in breach of the Code including Clause 2 and was required by the Appeal Board to issue a corrective statement to all UK attendees.**

**The complainant stated that Astellas colleagues recently provided training on the outcome of Case AUTH/2747/1/15 and its learnings and a 'town hall' meeting was convened, where a very senior employee (identified by job title) of Astellas Pharma Europe discussed the matter, albeit in a very dismissive manner.**

**The complainant stated that it was extremely alarming and concerning that the account given to the PMCPA was knowingly false and intentionally misleading. In its response to Case AUTH/2747/1/15 Astellas claimed that all invitees were identified and grouped based on their 'clinical expertise' and 'experience of treating patients with mCRPC' (metastatic castration – resistant prostate cancer). Unfortunately, nothing was further from the truth and Astellas knew that but deliberately chose to conceal it from the PMCPA. The complainant provided a copy of the briefing given by Astellas to its affiliates which stated that all 30 opinion leaders chosen by each affiliate had to be; 'mid to top level opinion leaders with the potential to be local product champions'. Furthermore it was requested that they be 'data naïve'. The complainant alleged that this directly contradicted the claim made that they be chosen based on their clinical expertise.**

**The complainant stated that it was also disappointing that Astellas had still not learnt from rulings of breaches of the Code including Clause 2, and that the company had deliberately misled the PMCPA about a very serious complaint. The complainant urged the PMCPA to consider more serious sanctions including an audit of the company's procedures, a public reprimand and possible suspension or exclusion from membership of the ABPI.**

**The detailed response from Astellas Pharma Europe is given below.**

**The Panel noted the outcome of Case AUTH/2747/1/15 and that the Panel had ruled Astellas Europe in breach of the Code including Clause 2 in relation to arrangements for a meeting. The Panel had also reported the company to the Code of Practice Appeal Board. The Panel's rulings were not appealed. The Appeal Board required Astellas Europe to issue a corrective statement to UK attendees. This was issued on 1 July 2015.**

The Panel noted that the meeting at issue in Case AUTH/2747/1/15 had been run by Astellas Europe. The complaint concerned arrangements for UK attendees. In this regard the Panel noted that Astellas UK was responsible for the acts/omissions of its affiliates including its UK based European headquarters. In the Panel's view this remained the position even if the UK based European affiliate had responded directly to the complaint. In its response to Case AUTH/2780/7/15 Astellas Europe explained that Astellas UK and Astellas Europe had decided that the European affiliate should respond to the complaint. Correspondence in relation to Cases AUTH/2747/1/15 and AUTH/2780/7/15 had consequently been sent directly to Astellas Europe. The Panel noted the company's submission about the involvement of the UK company with the response to Case AUTH/2747/1/15 prepared by Astellas Europe. The Panel noted the position of Astellas UK in relation to the present complaint remained as set out above.

The Panel noted that the criteria used to select advisory board members to attend the meeting in question must stand up to scrutiny and relate solely to their ability to provide expertise to the company. The Panel considered that three emails sent in September 2013 and October 2013 were wholly unacceptable in relation to the criteria to be used to identify potential advisory board members. All the emails and/or their attachments listed above referred to invitees being mid to top level product opinion leaders with the potential to be local product champions within the relevant market and data-naïve customers ie those who had not been involved in any Astellas Europe or national/local advisory board meetings prior to the Pan EU Expert Meeting.

A presentation to the Oncology Steering Committee (5 February 2013) referred to the success of the Pan – European Uro-oncology Advisory Board held in Barcelona in November 2012. It stated that the proposed structure of future meetings was discussed/agreed by a UK medical employee. This presentation referred to the aims and suggested target audience for 13/14 pan European advisory board meetings as:

#### 'Objectives for meeting

- Increase Astellas' profile in the field of oncology
- Communicate Astellas' strategy and oncology pipeline to key target customers
- Communicate Xtandi and tivozanib data and common set of messages to EU affiliates' key target customers
- Gain an increased understanding of the current landscape in RCC and prostate cancer & the challenges Astellas will face when launching Xtandi and tivozanib in the EU

#### Target audience for meeting

- Mid – top level product OLs – those with the potential to be local product champions within the relevant EU markets
- Data – naïve customers, ie those who have not been involved in any APEL or national/local advisory board meetings prior to the pan EU ad board meeting
- 10 per affiliate: 5 prostate/Xtandi and 5 RCC/tivozanib\*

\*Turkey – 10CRPC OLs.'

The emails sent to the UK affiliate which reflected the selection criteria set out above, the email which the UK senior employee forwarded to UK managers, and the responses from this team compounded the unacceptability of the arrangements. In that regard the Panel noted the email from one of Astellas UK staff identifying health professionals who met these unacceptable criteria included '[city] is one of ... main key accounts', '...one of our high users and would respond well to such a meeting...', '... is influential at a [city] level and more and more nationally with time' and 'This is a business move ... barely sees industry, not using prechemo abi and once using he rarely changes'. The reserve nominations included '... I believe he has the reputation with us for being an abi man, however, this would give us the opportunity to convert him to the new way and '...is on our list and is influential, and would be good to engage at this level'.

The Panel did not accept Astellas Europe's submission in the case now under consideration that its provision of an incomplete and in the Panel's view misleading response was unintentional given Astellas' decision not to include the unapproved criteria following the dispatch of what Astellas described as a revised corrective email (December 2013). The Panel noted Astellas Europe's submission that it did not include the initial unapproved criteria in its response to Case AUTH/2747/1/15 as these were not the ultimate final criteria communicated to affiliates. It further noted the company's submission that there was no consideration at all as to whether the emails of 5 September and 17 October should be submitted as part of its response to the previous case, Case AUTH/2747/1/15. Astellas Europe acknowledged that its investigation into that complaint was inadequate.

The Panel was extremely concerned that Astellas Europe appeared to consider that ultimate revised final selection criteria had been communicated. In the Panel's view that was not so. Neither of the two emails dated 12 December sent from Astellas Europe contained revised selection criteria. The Panel noted Astellas Europe's submission that the teleconference held on 12 December discussed the revised selection criteria for attendees. In the Panel's view this should have been made abundantly clear in the emails of 12 December. Astellas Europe had not provided detailed information regarding the discussion on the teleconference. Given its comments above the Panel was not at all surprised by Astellas Europe's submission that none of its affiliates had subsequently requested any changes to those nominated as attendees. It was hard to understand why such a fundamental change to the selection criteria had not been made clear at the outset in either of the emails.

The Panel noted that the original selection criteria as set out in the three emails and the presentation to the Oncology Steering Committee dated 5 February 2013 were directly relevant to the subject matter of the complaint in Case AUTH/2747/1/15. In the Panel's view Astellas Europe had therefore provided not only an incomplete response to that complaint but also a misleading one.

The Panel noted Astellas Europe's submission that the final certification did not take place until the day before the meeting took place (26 February 2014) after health professionals had been selected and invitations sent.

In addition to the provision of an incomplete response, the Panel noted Astellas Europe's submission that it was now apparent that its representatives had misled the Appeal

Board when the report was considered as the UK sales force had been involved in the nomination process.

The Panel noted Astellas Europe's submission that concerns had been raised in November 2013 and that in January 2014 it had received an anonymous complaint about the meeting which had been dealt with by the issuing of the revised selection criteria and thus no further action was taken. The Panel noted its comments above about the revised selection criteria and their communication. The Panel also noted that Astellas Europe's response to the Panel's request for further information was different to its initial submission in relation to whether the company knew about the emails and the changes to the selection criteria for attendees and had decided not to provide them or whether the company had not asked staff for materials etc other than those in the Zinc system. In the Panel's view Astellas had either not paid sufficient attention to ensuring that all relevant information had been supplied in its response to Case AUTH/2747/1/15 or had made a conscious decision to omit relevant details from that response. The Panel noted Astellas Europe's most recent submission in this regard that it had not considered the material at all.

The Panel was extremely concerned and disappointed by the conduct of Astellas Europe and Astellas UK. The integrity of self-regulation relied upon the provision of complete and accurate information by pharmaceutical companies. The Panel considered that the failure to provide all the information and the misleading nature of what was submitted in Case AUTH/2747/1/15 meant that high standards had not been maintained. A breach was ruled as acknowledged by Astellas Europe. The circumstances brought discredit upon and reduced confidence in the pharmaceutical industry. The Panel ruled a breach of Clause 2 as acknowledged by Astellas Europe.

In relation to the allegations about the discussion of the case by a very senior employee of Astellas Europe, the Panel noted the comments made by staff interviewed about meetings which this individual had attended. It appeared that these were not 'Astellas town hall' meetings as stated by the complainant. It was not clear what the meeting referred to by the complainant was but the complaint was clear it was a meeting where this individual discussed the matter. The Panel was concerned that the interview guide for discussion with employees appeared to be biased and designed to encourage staff to confirm that they were impressed by the training and the 'Tone from the top'. Bearing in mind the difficulties for staff in being critical of senior management, the Panel was very concerned that a very senior employee of Astellas Europe's comments on the outcome of Case AUTH/2747/1/15 were viewed as dismissive and/or that the matter was not taken seriously enough. This was compounded by the serious nature of that case. The details set out in the collated interview feedback master document appeared to be different to those provided elsewhere in the company's response. Nonetheless it was clear that despite the content and tone of the interview guide, certain staff were concerned about the impression given. The Panel was also concerned that staff recalled the phrases 'we were trying something different' and 'there are large grey areas in application of the code'. The Panel disagreed with the latter comment in relation to Case AUTH/2747/1/15 as the requirements for advisory boards and other such meetings were clear in the Code, supplementary information and guidance issued by the PMCPA.

The Panel considered, given the seriousness of Case AUTH/2747/1/15, it was completely unacceptable in the companies' discussion of that case for a very senior employee of Astellas Europe to give any impression that he and/or the company was dismissive of

the Panel's rulings and the Appeal Board's consideration of the report from the Panel. The Panel considered that in this regard high standards had not been maintained and ruled a breach. In addition the Panel considered that the circumstances brought discredit upon and reduced confidence in the pharmaceutical industry. The Panel ruled a breach of Clause 2. These rulings were upheld on appeal by Astellas Europe.

The Panel considered that the circumstances regarding the failure to provide comprehensive, accurate information, the misleading nature of the submissions in Case AUTH/2747/1/15, the relevance of the omitted material and the discussion of the outcome of the case by Astellas Europe raised serious concerns about the companies' procedures. In this regard the Panel noted Astellas Europe's submission about its certification of the arrangements the day before the meeting in question. It also noted the Appeal Board's comments when considering the report from the Panel in Case AUTH/2747/1/15 that the company's standard operating procedures were either unclear or not followed and its questions over the rigour of Astellas Europe's certification process. This case also raised fundamental concerns regarding Astellas Europe and Astellas UK's approach to compliance and self-regulation.

The Panel noted its comments above regarding the position of Astellas UK and Astellas Europe in relation to this case. The Panel considered that its serious concerns warranted reporting Astellas Europe and Astellas UK to the Appeal Board under Paragraph 8.2 of the Constitution and Procedure.

In relation to the report from the Panel, Astellas Europe contacted the PMCPA in September to advise that it had recently discovered information which the company wished to provide to the Appeal Board in relation to its consideration of the report from the Panel. The Chairman of the Appeal Board agreed that Astellas Pharma Europe could submit further information in relation to the report. The information did not relate to Astellas UK.

Astellas Europe stated that it had conducted a number of staff interviews as part of its continued human resources investigation and an email had been discovered which it considered to be the source of the concerns that were raised in November 2013 about the advisory board at issue in Case AUTH/2747/1/15.

The email, from a senior employee at Astellas Europe was dated 26 October 2013 and indicated that the sender was instructing the team to remove an unacceptable objective for the advisory board from the meeting agenda in order to 'smooth the passage' of the meeting through the approval process, but unfortunately made it clear that this was still a key objective of the advisory board.

Astellas Europe referred to the background and submitted that the email indicated that there was a conscious decision by one individual to circumvent the established approval process in order to incorporate an unacceptable objective in to an advisory board.

Astellas Europe submitted that the email appeared to be the trigger for the activities that took place in late 2013 to reassess the meeting and address the concerns raised. Two of the four members of staff in receipt of the email of 26 October 2013, whilst not sharing or discussing the email directly with anyone, raised their concerns about the meeting. The activities in November and December 2013 were as a consequence of this in an attempt to correct the issues raised eg the teleconference and emails of 12 December 2013.

**Astellas Europe as an organisation stated that it was not aware of the emails until 22 September 2015 which was why they were not submitted in the company's response to Case AUTH/2780/7/15. This was particularly disappointing, given that the individual in question was asked for all relevant information.**

**At the consideration of the report Astellas Europe and Astellas UK stated that the companies recognised that the investigation and response to Case AUTH/2747/1/15 was inadequate. The companies submitted that there was no dishonesty or deliberate attempt to mislead. The investigation had identified that an individual senior member of staff central to this situation withheld key information from Astellas Europe, the Panel and Appeal Board. Immediate action had been taken to address the conduct of this senior member of staff. Astellas incorrectly assumed that there was no sales involvement in nominating UK health professionals to attend the advisory board and therefore it unintentionally provided inaccurate information to the Appeal Board.**

**Astellas accepted the Panel's rulings of breaches of the Code and deeply regretted that it had brought disrepute on the pharmaceutical industry.**

**Astellas Europe stated that it had already undertaken a number of measures and gave details of its key compliance activities since the completion of Case AUTH/2747/1/15. Details were provided.**

**The Appeal Board noted the Panel's comments and rulings including its ruling of a breach of Clause 2 and the outcome of the appeal where the Appeal Board upheld a second Panel ruling of a breach of Clause 2. The Appeal Board was extremely concerned about the approach to compliance and poor communication across Astellas Europe and Astellas UK.**

**The Appeal Board noted the Panel's comments that the original selection criteria for Astellas Europe's Pan-European Uro-oncology Advisory Board Meeting were directly relevant to the subject matter of the complaint in Case AUTH/2747/1/15 yet these had not been provided by the company in its response to that case.**

**The Appeal Board was also very concerned about why the email dated 26 October 2013, sent by the senior employee of Astellas Europe was not previously provided. The Appeal Board noted from Astellas that two recipients of the email had raised concerns about the meeting back in 2013 but they had not disclosed the email itself. Astellas stated that the email was handed to senior management on 22 September 2015. The Appeal Board was concerned that such relevant information had not surfaced until this late stage.**

**The Appeal Board was very concerned about the culture of the organisations and that despite a prior internal complaint raising the issue it had taken two complaints under the Code and a late submission of evidence in the present case to produce comprehensive information concerning selection of the delegates for the meeting at issue.**

**The Appeal Board was concerned that the arrangements had been reviewed and approved by the UK affiliate. Astellas Europe certified the arrangements the day before the advisory board at issue took place.**

The Appeal Board considered that Astellas had provided not only an incomplete response to the original complaint but also a misleading one. The Appeal Board considered that self-regulation relied upon the provision of complete and accurate information by pharmaceutical companies. Astellas's omission was totally unacceptable. The Appeal Board decided that in accordance with Paragraph 11.3 of the Constitution and Procedure that both Astellas Europe and Astellas UK should be publicly reprimanded for this failure.

The Appeal Board noted that the UK health professionals who attended the meeting had been provided with a corrective statement and a case report which was misleading. This was totally unacceptable. Consequently the Appeal Board decided, in accordance with Paragraph 11.3 of the Constitution and Procedure, to require Astellas Europe and Astellas UK to issue a corrective statement to all the UK attendees at the meeting to clarify the position. The corrective statement should refer to both case reports. Under Paragraph 11.3 details of the proposed content and mode and timing of dissemination of the corrective statement must be provided to the Appeal Board for approval prior to use. [The corrective statement appears at the end of the report.]

The Appeal Board also decided that, given all of its concerns about the conduct of Astellas as set out above, to require, in accordance with Paragraph 11.3 of the Constitution and Procedure, an audit of both Astellas Europe and Astellas UK's procedures in relation to the Code. The audit would take place in December 2015. On receipt of the audit report, the Appeal Board would consider whether further sanctions were necessary including the possibility of reporting the companies to the ABPI Board of Management (Paragraph 12 of the Constitution and Procedure).

Astellas Pharma Europe and Astellas UK were each audited in December 2015 and on receipt of the report of the audits, the Appeal Board was extremely concerned that despite a very critical report that highlighted numerous serious concerns including the companies' cultures and a reference to Astellas Europe's institutional failure with respect to compliance, neither Astellas Europe nor Astellas UK provided any detail on when and how each would address those concerns.

The Appeal Board decided that both companies should be re-audited but it deferred setting a date for such until each had provided a detailed compliance action plan and comprehensive response to the recommendations in the report of the audits. The Appeal Board discussed further sanctions including, again, whether there should be a report to the ABPI Board. The Appeal Board concluded that on receipt of the report for the re-audits it would decide whether further sanctions were necessary.

The companies subsequently provided a further detailed response as requested. The Appeal Board noted that the companies would need time for their stated compliance objectives to be completed or get underway. In that regard the Appeal Board decided that Astellas Pharma Europe and Astellas UK should each be re-audited in September 2016 by which time both would be expected to demonstrate significant improvement.

During the Code of Practice Appeal Board's consideration of the audit reports for Astellas Europe and Astellas UK (25 February 2016) it noted a letter from Astellas Europe (17 February) which stated that new information had been discovered as a result of further investigation which would assist the understanding of the full circumstances of these cases and this would be sent to the PMCPA.

On receipt of further information from Astellas Europe the original Panel was reconvened to consider the matter.

The detailed response from Astellas Europe is given below and included a report by external counsel which was asked by Astellas Pharma Inc to conduct an investigation.

The Panel noted the circumstances surrounding Cases AUTH/2747/1/15 and AUTH/2780/7/15, the reports to the Appeal Board, the findings of the audits, particularly those relevant to Astellas Europe, and the additional information now provided by Astellas Europe. The companies were to be re-audited in September 2016.

The Panel noted that the additional information was provided by, and concerned acts and omissions by, Astellas Europe. The Panel noted that Astellas Europe was not a member of the ABPI, although it was a member of EFPIA. Astellas UK was a member of the ABPI. The Panel had previously noted that Astellas UK was responsible for the acts/omissions of its affiliates that fell within the scope of the Code including its UK based European headquarters. In the present matter, the Panel noted that the position of Astellas UK remained as set out above.

The Panel noted all the concerns and comments it had raised previously. It was appalled at the conduct of senior managers as revealed in the additional information in relation to the two cases and resulting audits. Senior managers failed to provide full and accurate details to the Panel, the Appeal Board and the Authority in relation to the audits. Some very important details, although hinted at by the Panel, the Appeal Board and by the Authority in the report of the audits, had only come properly to light as a result of the follow-up investigation ordered by Astellas Japan and carried out by an external counsel. This might, in part, have been triggered by the audits including the conversation the PMCPA had with the CEO and President Astellas Group.

The report from external counsel stated that all those involved in compiling the information and drafting the response to Case AUTH/2747/1/15 were aware of the existence of the original selection criteria, as on 30 January 2015 senior employees' attention was drawn to the email which set out the original selection criteria. This was inconsistent with Astellas Europe's original response.

The report from external counsel noted that the company's investigation following receipt of the second complaint (Case AUTH/2780/7/15) was inadequate. The external counsel report noted that the failure to conduct a thorough fact-finding exercise at any time following the first PMCPA complaint was concerning and was even more troubling given the number of senior staff who knew exactly where to look for the relevant material. Further details about the content of the report from the external counsel appear below.

The Panel considered that the additional information demonstrated that a number of individuals in Astellas Europe had not provided complete and accurate information. That this included very senior employees was extremely concerning. Astellas Europe's conduct was completely unacceptable. The report of the audits had found that there was an institutional failure with respect to compliance; a finding which, in the Panel's view, was now compounded by the additional information including the report by external counsel. The failings of Astellas Europe, as demonstrated by the additional information,



went beyond, and were arguably even more serious than, those outlined in the report of the audits. The latest information demonstrated that Astellas Europe staff had lied about the original selection criteria on a number of occasions and not limited to Astellas Europe's response to the complaints but including when interviewed individually by members of the Authority at the audit, when they appeared before the Appeal Board in relation to the reports from the Panel in both cases and at the appeal in Case AUTH/2780/7/15. The failure to provide accurate, complete information at an audit and to the Appeal Board was a very serious matter. The truthfulness and accuracy of such comments and submissions to the Authority was fundamental to the integrity of self-regulation. It was remarkable that the individuals concerned had not provided the correct information sooner despite having had every opportunity to do so; the true position only emerged after those from the PMCPA carrying out the audits had spoken to the Japanese parent company and a report from external counsel was commissioned. The Panel was also concerned about the newly revealed breadth of compliance failures such as flawed processes including human resources processes wherein vital compliance material was not recognized as such, and the apparently unfettered influence of the named senior individuals upon matters such as disciplinary investigations. The Panel noted that very senior employees had left Astellas Europe. The Panel decided that it would report Astellas Europe to the Appeal Board under Paragraph 8.2 of the Constitution and Procedure for it to consider in relation to Paragraphs 11.3 and 11.4 of the Constitution and Procedure. Astellas UK would be advised accordingly.

The detailed comments from Astellas Europe and Astellas UK on the report from the Panel appear below.

In summary the representatives from Astellas Europe sincerely apologised for the significant cultural and compliance failings created and caused by the actions and behaviours of some of its very senior managers. Globally Astellas viewed the current position as a corporate crisis. The newly appointed President of Astellas Europe stressed his commitment to improve corporate culture such that ethics and compliance were embedded throughout the organisation. Some of that cultural change would come through the appointment of new people into key roles.

The UK company was committed to working closer with Astellas Europe to clarify responsibilities and to ensure that the UK approved and certified any activity undertaken by its European affiliates that involved a UK health professional or took place in the UK. The company would also take responsibility for any future complaints under the Code about such activities.

The Appeal Board welcomed the full apology made by the representatives of Astellas Europe at the consideration of the report, particularly as no apology was included in the papers for the case. However, the Appeal Board considered that such multiple organisational and cultural failings meant that this was one of the worst cases it had ever had to consider. There was an institutional failure with respect to compliance. Very senior staff had lied and there was deception on a grand scale. The Appeal Board was appalled and astonished that senior managers from Astellas Europe had made a concerted attempt to deceive it and the PMCPA. In that regard the Appeal Board considered the PMCPA's foresight to interview the Global CEO and President of Astellas Inc during the audit was pivotal in bringing these failings to light. It was a truly shocking state of affairs. The Appeal Board noted that these concerns did not relate to Astellas UK.

**This was the third time Astellas Europe had been reported to the Appeal Board by the Panel and the second time Astellas UK had been reported to the Appeal Board by the Panel (including Case AUTH/2747/1/15).**

**The Appeal Board whilst recognising the difficulties of the situation, considered that Astellas UK should have attempted to exercise greater control on compliance matters in relation to the meeting at issue, the investigation of and response to the complaints and the Panel's reports to the Appeal Board. This was especially important given that Astellas UK was responsible for the acts/omission of its affiliates that fell within the scope of the Code including its UK based European headquarters. Given the information about the lies and deception, it was not surprising that Astellas Europe had asserted itself and taken the lead in responding to Cases AUTH/2747/1/15 and AUTH/2780/7/15.**

**The Appeal Board noted that Astellas Europe, as a member of EFPIA, was bound by the codes of EFPIA member associations including any applicable sanctions.**

**The Appeal Board considered that the integrity of self-regulation was reliant upon pharmaceutical companies providing complete and accurate information. The conduct of senior staff at Astellas Europe had been totally unacceptable and potentially harmful to self-regulation in this regard. It was also disappointing that Astellas UK had not taken firm action. There were multiple failings in these cases. The Appeal Board decided that in accordance with Paragraph 11.3 of the Constitution and Procedure that both Astellas Europe and Astellas UK should again be publicly reprimanded for this failure.**

**The Appeal Board noted that the UK health professionals who attended the meeting had been provided with two corrective statements and case reports which, given the emergence of new information, gave a misleading account of the arrangements for the meeting at issue. This was wholly unacceptable. Consequently the Appeal Board decided, in accordance with Paragraph 11.3 of the Constitution and Procedure, to require Astellas Europe and Astellas UK to issue a fresh corrective statement to all the UK attendees at the meeting to clarify the position. This would be the third corrective statement. [The corrective statement appears at the end of the report.]**

**The Appeal Board also decided, given the seriousness of the failings, its concerns about the conduct of Astellas as set out above and the responsibility of Astellas UK for its parent company, to report Astellas Europe and Astellas UK to the ABPI Board of Management. This was in accordance with Paragraph 12.1 of the Constitution and Procedure.**

**The ABPI Board noted that breaches of the Code had been ruled including Clause 2. The companies had been reported to the Appeal Board and both had been publicly reprimanded and required to issue corrective statements. The companies had been audited in December 2015 and were to be re-audited in September 2016.**

**The ABPI Board was extremely concerned at the multiple organisational and cultural failings at Astellas. There was an institutional failure. Very senior staff at Astellas Europe had lied and there was deception on a grand scale which was appalling and shocking.**

The totally unacceptable behaviour of senior staff at Astellas Europe was potentially harmful to the integrity of self-regulation which relied upon companies providing complete and accurate information. The ABPI Board noted that Astellas UK was the member of the ABPI and that Astellas UK was responsible for the acts/omissions of affiliates that fell within the scope of the Code including its UK based European headquarters.

The ABPI Board decided that Astellas UK should be suspended from membership of the ABPI for a period of 12 months commencing 24 June. The ABPI Board also decided that it wanted sight of the reports of the September 2016 reaudits of Astellas UK and Astellas Europe so that it could review the position, including the length of the suspension, before the end of 2016. The reaudits must show demonstrable improvements at both companies particularly in relation to corporate culture.

Astellas UK and Astellas Europe were re-audited in September 2016 and the report of the audits was considered by the Appeal Board in November.

The Appeal Board noted that although both companies had worked hard to implement the recommendations from the previous audits and to ensure compliance was truly embedded, there was still work to do.

With regard to Astellas Europe, the Appeal Board noted that the institutional failure with respect to compliance was starting to change. Both companies had, *inter alia*, issues with certification. The Appeal Board decided that both should be re-audited in April 2017 and on receipt of the report for those re-audits it would decide whether further sanctions were necessary.

At its meeting in December, the ABPI Board reviewed the progress made by both companies and the work still to be completed noting that it took time to change culture and to truly embed compliance. It noted the Appeal Board's decision that both companies should be re-audited in April 2017. Although the ABPI Board was encouraged by the improvements and progress made by both Astellas Europe and Astellas UK it decided that the suspension of Astellas UK from membership of the ABPI should continue. The ABPI Board would review the position in June after the re-audits.

Astellas UK and Astellas Europe were re-audited in April 2017 and the report of the audits was considered by the Appeal Board in May 2017.

The Appeal Board noted that Astellas UK and Astellas Europe were now working more closely and there was more open communication with staff. Both companies had been working to implement the recommendations of the previous audits and to ensure compliance was embedded. However, the Appeal Board noted the number of issues highlighted in the report and that there was still much work to be done.

The Appeal Board accepted that it took a long time to change culture but it was not convinced that progress was being made at an appropriate speed particularly given the issues that had come to light in Cases AUTH/2883/10/16, AUTH/2939/2/17 and AUTH/2940/2/17. This was particularly worrying given the level of scrutiny the companies were under. In the view of the Appeal Board, Astellas had much work still to do.

In relation to Case AUTH/2780/7/15 the Appeal Board decided that both companies should be re-audited in October 2017 at the same time as the audits required in Cases AUTH/2939/2/17 and AUTH/2940/2/17 and the re-audit in Case AUTH/2883/10/16 (Astellas UK only).

The Appeal Board noted the outcome of the audit in Case AUTH/2883/10/16 and the re-audits in Case AUTH/2780/7/15, the decisions to report Astellas UK to the ABPI Board in relation to Case AUTH/2883/10/16 and Astellas UK and Astellas Europe in relation to Cases AUTH/2939/2/17 and AUTH/2940/2/17. It also noted its concerns regarding the lamentable lack of concern for patient safety and wholly inadequate oversight and control. Whilst noting this was a matter for the ABPI Board, the Appeal Board's view was that Astellas UK was not ready to resume membership of the ABPI and the suspension should continue.

At its meeting in June 2017 the ABPI Board agreed with the Appeal Board's comments and concerns about the re-audits in April 2017.

The ABPI Board noted and endorsed the Appeal Board's views about the total failure of the companies' systems in relation to the control of prescribing information, the lamentable lack of concern for patient safety, wholly inadequate oversight and control and initial lack of urgency. It was a woeful state of affairs.

The ABPI Board gave serious consideration to expelling Astellas UK from membership of the ABPI. However, it noted the commitments from Astellas Europe, the global company and of the new UK General Manager. The companies had made voluntary admissions and it was now imperative that the October re-audits showed significant progress.

The ABPI Board decided that it would extend the suspension of Astellas UK from membership of the ABPI for another 12 months. This further period would run uninterrupted from the initial period of suspension and would then amount to the maximum suspension (two years) allowed under the ABPI Articles of Association.

The ABPI Board also decided that it wanted sight of the report of the October 2017 re-audits of Astellas UK and Astellas Europe so that it could review the position before the end of 2017. If the report of the re-audits did not show significant improvement and progress at both companies, then the ABPI Board would consider expelling Astellas UK from membership of the ABPI. The companies should consider undergoing an external assessment of progress, particularly in relation to risk management of compliance in the broadest sense, ie including matters beyond the scope of the Code, with the outcome to be available at the time of the October 2017 re-audits.

The ABPI Board also decided that the MHRA should be advised of the ABPI Board's very serious concerns about the conduct of Astellas UK and Astellas Europe particularly in relation to the matters concerning patient safety. EFPIA should also be updated and asked to ensure the EFPIA Board was informed of the position.

Astellas UK and Astellas Europe were re-audited in October 2017 and the report of the re-audit was considered in November. The Appeal Board noted that as these were the fourth audits of the companies and given that Astellas UK was currently suspended from membership of the ABPI, it expected substantial progress and improvements from both companies. This expectation had not been met. The Appeal Board acknowledged that

some progress had been made. The companies must take prompt action to implement the findings and recommendations in the report of the October 2017 re-audits.

The Appeal Board accepted that it took time to change a company's culture. In this regard, the Appeal Board noted that there had been positive changes in the company culture. However, it was not convinced that the expected progress was being made, especially since the April 2017 re-audits.

Overall, the Appeal Board's view was that the rate of progress was inadequate and that the companies were not where they should be. There was still much work to do. The Appeal Board queried whether there was an element of structural inertia or perhaps fear of wrongdoing which was inhibiting or slowing the rate of progress.

Despite its criticisms, the Appeal Board noted the positive steps taken by the leadership of Astellas to engage more broadly with staff and drive changes.

The Appeal Board decided that both companies should be re-audited in April 2018. At which point it expected the 2018 global staff survey to demonstrate improvements at Astellas Europe and Astellas UK.

Whilst noting that this was entirely a matter for the ABPI Board, the Appeal Board's view was that if the report of the October 2017 re-audits and Astellas' response had come at the end of the two year suspension limit, then Astellas would have fallen well short of the standard required to resume membership of the ABPI. Unless substantial progress was seen in the report of the re-audits in April 2018, in the Appeal Board's view, Astellas UK would be at serious risk of a recommendation that it be expelled from membership of the ABPI.

The ABPI Board noted the Appeal Board's comments and concerns about the re-audits in October 2017 and the additional information provided by Astellas.

With regard to the external assessment of progress, particularly in relation to risk management of compliance in the broadest sense ie including matters beyond the scope of the Code, the ABPI Board noted the information provided by Astellas.

Following a change in tone from the top of Astellas, the ABPI Board recognised that meaningful progress had been made by the companies. The ABPI Board understood the difficulty inherent in making wide-sweeping cultural changes, and how long it took for those changes to become fully embedded within a large organisation. However, the ABPI Board acknowledged Astellas' clear commitment to further improvement.

The ABPI Board noted Astellas' statement that its materials were compliant in May 2017 in relation to issues of patient safety.

The ABPI Board also decided that it wanted sight of the report of the April 2018 re-audits of Astellas UK and Astellas Europe so that it could review the position before the end of the current suspension in June 2018.

The ABPI Board decided that taking all the circumstances into account it would take no further action at this stage in relation to the expulsion of Astellas from membership of

the ABPI. The suspension from membership of the ABPI would remain in place until June 2018.

The ABPI Board also decided that the MHRA should be advised of the position. EFPIA should also be updated and asked to ensure that the EFPIA Board was informed of the position.

Astellas UK and Astellas Europe were re-audited in April 2018 and the report of the re-audits was considered in May 2018.

The Appeal Board noted the detailed responses from Astellas to the report of the April 2018 re-audits including that it was an accurate reflection of the work undertaken.

The Appeal Board noted the results of the 2018 staff survey and the progress made. Numerical increases had been shown in a number of parameters since the previous survey in July 2017. There were concerns about the comments made by staff. The Appeal Board also noted the differences in the Astellas UK results which were generally better than the Astellas Europe results. The Appeal Board considered that the Astellas Europe management committee scores although improved were still not where they should be.

The Appeal Board noted the comments in the report of the April 2018 re-audits and considered that both the leadership of Astellas Europe and Astellas UK had engaged with staff to bring about progress. There was still work to be done. The Appeal Board noted one of the recommendations was that members of the leadership team at Astellas Europe should be held to account and be challenged on compliance matters.

The Appeal Board accepted that it took time to change a company's culture. In this regard, the Appeal Board noted that there had been further positive changes in the company culture and this needed to be continued. The Appeal Board noted that there had been some positive compliance initiatives. The discussion fora and communications continued and progress had been made including ensuring staff had time to complete training.

The Appeal Board noted that whilst as a percentage there had been a significant increase in the number of job bags, the overall number was still low. As Astellas increased its activities it must remain extremely vigilant to compliance requirements in particular in relation to certain higher risk activities such as patient support programmes, product launches etc. The true test of the compliance framework in Astellas and its approach would be when activity levels including higher risk activities were increased and the company was operating at business as usual.

The Appeal Board considered that, at long last, the re-audits in April 2018 showed that progress had been made and that the companies were building on momentum started in summer 2017. The Appeal Board was concerned that these were the fifth audits of each company and that the first audits were in December 2015. It was extraordinary that it had taken so long to demonstrate meaningful change. The overall impression from the report of the April 2018 re-audits was that Astellas was showing improvement and momentum. However, whilst the companies had reached a certain level, given all the circumstances including that Astellas UK had been suspended from membership of the ABPI and that the Appeal Board still had concerns, the Appeal Board decided that Astellas Europe and

**Astellas UK should each be re-audited at the end of the first quarter of 2019 to ensure that the improvements and the momentum continued and were built upon.**

**On the information before it, and noting that Astellas UK was still to respond to the PMCPA in relation to matters raised following completion of the consideration of a complaint concerning Astellas UK, Case AUTH/2984/10/17, the Appeal Board decided that sufficient progress had been made by the companies such that the Appeal Board did not consider that it warranted a recommendation for the expulsion of Astellas UK from membership of the ABPI when the matter came before the ABPI Board on 5 June 2018.**

**In June 2018 the ABPI Board noted the comments from both the Appeal Board and Astellas.**

**The ABPI Board noted the limited information provided about matters raised in Case AUTH/2984/10/17. This was still to be considered by the PMCPA and the Appeal Board and was not before the ABPI Board for consideration.**

**The view of the Appeal Board was clear. The ABPI Board agreed with the Appeal Board's views and assessment of the re-audits and concluded that meaningful progress had now been made.**

**The ABPI Board believed that the culture in the companies had improved and noted that much of this had been led by the General Manager of Astellas UK. However, the Board recognised the importance of an ongoing commitment to ensure sustained culture change. On reviewing all the material, the ABPI Board had concerns about the sustainability of the changes made given that there had already been five audits/re-audits, and especially as further types of activity were still to be fully re-introduced across the companies.**

**The ABPI Board therefore decided that it wanted to see the report of the 2019 re-audits and be informed of major developments including the outcome of Case AUTH/2984/10/17.**

**In the circumstances, there was no need for the ABPI Board to consider expelling Astellas UK from membership of the ABPI. The suspension would end on 24 June 2018 and Astellas would revert to full membership of the ABPI.**

**The ABPI Board also decided that the MHRA should be advised of the position and that EFPIA should be updated and asked to ensure that the EFPIA Board was informed of the position.**

**Astellas UK and Astellas Europe were re-audited in April 2019 and the report of the re-audits was considered in May 2019.**

**The Appeal Board noted the detailed response from Astellas Europe and Astellas UK to the report of the April 2019 re-audits.**

**The Appeal Board noted two new senior appointments; a new President EMEA Operations who joined Astellas in July 2018 and a new General Manager, Astellas UK who was appointed from April 2019.**

The Appeal Board noted from the report of the April 2019 re-audits that it appeared that a more compliant culture was embedded within Astellas with improved communication. It was essential that this was maintained.

The Appeal Board considered that Astellas UK must ensure a proper professional approach to investigating and responding to any complaint under the Code such that the shortcomings in Case AUTH/2984/10/17 were not repeated. The Appeal Board noted that an audit had not been required in Case AUTH/2984/10/17. The case had, in accordance with established practice, been discussed as part of an examination of the company's culture at the re-audits.

The Appeal Board noted that these were the sixth audits/re-audits of each company and that the first audits were in December 2015. The Appeal Board considered that, on the information provided in the report of the April 2019 re-audits, it appeared that the companies had made further improvements, that this would be maintained and broadly the companies were where they should be. The Appeal Board, however, remained very concerned about the amount of time it had taken Astellas to reach this point. The Appeal Board noted that Astellas stated that it would follow up on the issues identified in the report of the April 2019 re-audits and it was committed to maintaining its approach to embedding a sustainable compliance culture. The Appeal Board noted a number of activities/actions were due to be undertaken. On the understanding that this work was completed, that the progress shown to date was continued and a company-wide commitment to compliance was maintained, the Appeal Board decided that, on the basis of the information in the report of April 2019 re-audits, no further action was required in relation to Case AUTH/2780/7/15, Case AUTH/2883/10/16, Cases AUTH/2939/2/17 and AUTH/2940/2/17.

The Appeal Board noted that the audit/re-audits in these four cases had been required by the Appeal Board. They had not been required by the ABPI Board. Nonetheless, the Appeal Board noted the ABPI Board's request to see the report of the April 2019 re-audits.

At the re-audits in April 2019 it was noted that the MHRA decided that Astellas advertising materials should be submitted for review. This was introduced for all new materials issued since 1 December 2018.

In June 2019 the ABPI Board received an update as requested. It noted the comments from both the Appeal Board and Astellas and the improvements made.

An anonymous and non-contactable complainant who appeared to be an employee of Astellas complained about the truthfulness of Astellas's response to Case AUTH/2747/1/15. Case AUTH/2747/1/15 concerned the arrangements for a meeting organised by Astellas Pharma Europe and held in Milan in February 2014. In that case the company was ruled in breach of the Code including Clause 2 and was required by the Appeal Board to issue a corrective statement to all UK attendees.

The complainant provided an email dated 5 September 2013 from an agency to an employee at the Astellas Turkey affiliate and copied to a senior employee at Astellas Europe and six others. It was headed 'email from [named employee]; 3rd Pan EU Expert meeting in February 2014'. This email referred to one attachment which was described as a 'top-line guide to the meeting'



which outlined the proposed process for the meeting. The email stated that it was asking each affiliate to provide details of 30 opinion leaders in priority order who should be mid to top level opinion leaders with the potential to be local product champions within the relevant market and data naïve customers ie those who had not been involved in Astellas Europe national/local advisory board meetings. There was also a request for an Astellas affiliate contact who could be approached concerning delegate nominations. The complainant did not provide a copy of the attachment.

## **COMPLAINT**

The complainant stated that Astellas legal and compliance colleagues recently provided training on the outcome of Case AUTH/2747/1/15 and its learnings. In addition, a 'town hall' meeting was convened, where a very senior employee of Astellas Europe discussed the matter, albeit in a very dismissive manner.

The complainant stated that it was extremely alarming and concerning that the account given to the PMCPA in the response by Astellas was knowingly false and intentionally misleading. In its response to Case AUTH/2747/1/15 Astellas claimed that all invitees and participants were identified and grouped based on their 'clinical expertise' and 'experience of treating patients with mCRPC' (metastatic castration – resistant prostate cancer). Unfortunately, nothing was further from the truth and Astellas knew that but deliberately chose to conceal it from the PMCPA. The complainant provided a copy of the briefing given by Astellas to its affiliates in which it was clearly stated that all 30 opinion leaders chosen by each affiliate had to be; 'mid to top level opinion leaders with the potential to be local product champions'. Furthermore it was requested that they be 'data naïve'. The complainant alleged that this directly contradicted the claim made that they were chosen based on their clinical expertise.

The complainant stated that it was also disappointing that Astellas had still not learnt from the rulings of breaches of the Code including Clause 2, and that the company had deliberately misled the PMCPA about a very serious complaint. The complainant urged the Authority to consider more serious sanctions and submitted that given the gravity and seriousness of this very deliberate lie, consideration should be given to an immediate audit of the company's procedures, a public reprimand and possible suspension or exclusion from membership of the ABPI.

When writing to Astellas Europe attention was drawn to Clauses 2 and 9.1.

## **RESPONSE**

Astellas Europe stated that it was disappointed to receive the complaint, as the company had measures in place, including an ethics help line, to facilitate the anonymous reporting of employee concerns and encouraged employees to raise such concerns. Astellas Europe supported employees who raised concerns and the company was committed to addressing anything which was not aligned with the requirements of the Code.

The email provided by the complainant dated 5 September 2013 was sent on behalf of Astellas Europe by the agency co-ordinating the organisation of the advisory board at issue in Case AUTH/2747/1/15 to the general manager of the Astellas affiliate in Turkey.

Before addressing the complaint, Astellas Europe provided background to the series of events leading up to the advisory board at issue in Case AUTH/2747/1/15. Some of the events had

only become apparent to Astellas Europe during the investigation into this complaint (Case AUTH/2780/7/15).

### ***Chronology of key events***

#### **4 September 2013**

During Astellas Europe's investigation of the present complaint, and as background to the email, the company discovered that a draft of this email was sent on 4 September 2013 by the agency organising the advisory board on Astellas Europe's behalf, to a senior employee in oncology at Astellas Europe, with a suggested text for an email to affiliate general managers which 'provides an overview and outline of the proposed process for the meeting, along with a request for the name of a contact in the affiliate who we can contact concerning nominations for the meeting'. This text was almost identical to that included in the email provided by the complainant and the selection criteria contained in both were based on those discussed in February 2013 at the Oncology Steering Committee (which consisted of representatives from Astellas affiliates in the Nordics, France, Germany, UK, Spain, Czech/Slovak, Italy and Poland). There was no record of Astellas Europe notifying the agency that the text was appropriate to send but the senior employee concerned recalled that he 'must have done'. A copy of the agency email and the presentation given at the Oncology Steering Committee in February 2013 were provided.

#### **5 September 2013**

Astellas Europe stated that the following day, 5 September 2013, a slightly amended version of the email was sent by the agency to the general managers, and in some cases the oncology business unit director (where this position existed) of the Astellas affiliates in Belgium, Hungary, Russia, South East Europe, Spain, France, Italy, Turkey and Portugal. The email, *inter alia*, noted that each Astellas affiliate was being asked to nominate health professionals to attend the advisory board and listed certain criteria for these potential attendees. Astellas Europe submitted that this appeared to be the email that the complainant provided.

#### **October 2013**

Astellas Europe stated that in October 2013 it was decided to expand the scope of the advisory board as it was considered important to gain advice from health professionals in countries that were likely to be an early launch market; the relevant countries were UK, Germany, the Nordics, South Africa and the Netherlands.

#### **9, 10 and 11 October 2013**

Astellas Europe stated that in October 2013 an email was sent to the UK affiliate asking for a key contact for the agency organising the meeting and inviting a member of the UK team to attend one of two teleconferences in relation to the meeting (to be held on 10 and 11 October 2013) 'to discuss the focus of the Feb meeting, and implications for the target audience at the meeting'. A member of the UK team was nominated, was sent and tentatively accepted an invitation to the teleconference on 11 October 2013. During the investigation of this complaint this member of the UK team confirmed that he attended the teleconference. A discussion was also held with the Astellas member of staff who ran this teleconference who confirmed that the criteria specified in the email of 5 September were not discussed. Reference to 'implications for the target audience at the meeting' was in relation to whether the attendees were oncologists, urologists and/or uro-oncologists.

**17 October 2013**

Astellas Europe stated that on 17 October 2013 an email was sent by the agency to a senior employee in Astellas UK reiterating the same criteria for selecting attendees that were in the email of 5 September. The email requested that the UK provide nominated health professionals by 23 October 2013.

Although not documented, Astellas Europe understood from Astellas UK that there were two main criteria used to select potential health professional participants:

- That they were either urologists (given that the anticipated change to the licence was going to bring enzalutamide in to an earlier timeframe for treatment, potentially one in which urologists would have a greater role)
- Or that they were oncologists who saw a high volume of patients in clinics and had very practical experience of treating patients that were chemo-naïve.

The reasoning behind these criteria were that enzalutamide, which had broadly similar efficacy data in comparison with the already licensed direct competitor but with some advantages in terms of dosing, administration, monitoring and quality of life, was expected to soon be licensed for chemotherapy-naïve patients. Astellas UK wanted to understand from clinicians with high clinical workloads if these factors would fundamentally change treatment paradigms, specifically around the lack of routine monitoring and the theoretical benefit of saving valuable clinic time. In theory there would be a significant advantage with enzalutamide but there were reports of many clinicians not observing the strict monitoring requirements of the competitor product. The UK needed to understand the 'real world' scenario.

**21 October 2013**

Astellas Europe stated that the investigation conducted in relation to this complaint highlighted that, unbeknown to, and without any briefing from, Astellas, this email was forwarded by the UK senior employee in its entirety on 21 October 2013 to a UK management team which consisted of the medical and commercial members noting that 'we need to get back with nominations of customers for this event'.

**22 and 23 October 2013**

The following day (22 October 2013) one of the commercial managers replied with a list of seven UK health professionals to be put forward in the nomination process. It could be seen from this email that wholly inappropriate language was used to describe these health professionals as potential advisory board participants eg '.....is one of the....main key accounts'; '....is one of our high users'; '...advocate...'; '...influential...'; '...this is a business move....'; '...barely sees industry...'. On 24 October 2013 another reply was received from another manager with a further 30 nominations.

**November 2013**

Astellas Europe stated that on 7 November 2013 a UK senior employee sent an email to the agency with the 39 finally nominated health professionals. On the same day the agency sent

out 'save the date' cards. During the investigation of this complaint Astellas Europe asked the UK affiliate to confirm who had nominated the further two health professionals above those nominated by the UK managers but the UK had no record of this.

In November 2013, concerns were raised internally about the advisory board. Further discussions took place and a decision was taken to issue a corrective email to address the inappropriate criteria previously communicated to the affiliates and to change the working groups from international sessions to national working group sessions at the meeting.

### **12 December 2013**

Astellas Europe stated that a teleconference was held on 12 December 2013 with affiliates involved in the advisory board to discuss a number of changes to the format and organisation of the meeting, one aspect being the revised selection criteria for attendees. Affiliates were asked, in the light of the revised selection criteria, to reassess whether the health professionals already nominated were appropriate. No affiliate changed the health professionals that they had nominated.

On the same day an email including revised selection criteria was sent to affiliates. Also a separate email was sent to affiliates asking whether they wanted to run their own workshop on the day of the advisory board meeting or run an Astellas developed workshop. This email also noted 'Please also let Astellas know by end of play on Monday the 16th December whether there are any issues from a national compliance perspective given the change from international working group sessions to national working group sessions at the meeting'; 'Please also discuss the meeting with your affiliate's compliance/zinc manager by the end of this week/beginning of next week and answer any questions that they have to ensure that the meeting is rapidly reviewed as soon as the meeting approval form becomes available on the system once again'.

### **17 December 2013**

Astellas Europe stated that on 17 December 2013 the UK senior employee confirmed that he had spoken to a senior Astellas UK medical employee who had given him 'enough comfort that this meeting was ok under the circumstances'. The discussion was in relation to the change from there being national rather than international workshops at the meeting. The UK senior employee confirmed the UK would be 'moving ahead and would appreciate starting with the Astellas structure for content and agenda but would chair and run ourselves'.

### **30 December 2013**

Astellas Europe stated that on 30 December 2013 formal invitations were sent to potential attendees.

### **January 2014**

Astellas Europe stated that in January 2014, an anonymous internal complaint was received which consisted of a copy of an email very similar to the one provided by the complainant in this case. No other documentation was received. Astellas Europe considered that it had dealt with this in the previous December by issuing the revised selection criteria and no further action was taken.

### **February 2014**

Astellas Europe stated that its investigation in relation to this complaint highlighted that on 14 February 2014 an email was sent by a member of the Astellas UK medical team to the UK senior employee. This email asked whether or not 'we believe this group to have been appropriately selected'. A discussion took place between them whereby the UK medical employee was reassured with the criteria provided above (see under 17 October 2013).

The advisory board meeting was finally certified by Astellas on 26 February 2014, the day before the meeting started.

In response to the request to provide copies of any material used to debrief staff on the meeting at issue in Case AUTH/2747/1/15, Astellas Europe provided copies of a meeting report and a report on the results of a survey conducted with the meeting attendees.

### **Allegations regarding its response in Case AUTH/2747/1/15**

Astellas Europe acknowledged that the suggested criteria in the presentation of February 2013 and the criteria provided in the email of 5 September 2013 and the email to the UK on 17 October 2013 were wholly inappropriate in that they described potential attendees as having the 'potential to be local product champions' and that they should be 'data naïve'; these were not suitable criteria for choosing advisory board attendees. These emails should not have been sent, given their content and the fact that the objectives for the advisory board and the criteria for selecting potential attendees had not yet been formally approved on Zinc. The communications were very disappointing as they clearly fell below the standard expected of Astellas employees and their compliance with the Code.

Concerns were raised internally about the inappropriate nature of the email and a revised, corrective email was sent in December 2013 to the affiliate contacts for the advisory board. Astellas Europe did not include the initial, unapproved, criteria in its response to the complaint in Case AUTH/2747/1/15 as these were not the ultimate final criteria communicated to the affiliates to identify health professionals that they considered should attend the advisory board; the criteria communicated were those included in the letter to the Authority dated 6 February 2015 ie that they should be local experts in the field of mCRPC in their country, with personal experience of treating patients with mCRPC. These criteria were also included in the approval form for the meeting which was reviewed and approved by all relevant affiliates and ultimately certified by Astellas Europe signatories.

However, Astellas Europe acknowledged that the emails of 5 September and 17 October 2013, as well as the presentation from February 2013, were relevant to the complaint in Case AUTH/2747/1/15 and therefore the response to that complaint was incomplete. Astellas Europe submitted that that said, the selection criteria used by the UK was broadly similar to that provided to the Panel and the Appeal Board in its response to Case AUTH/2747/1/15.

Astellas Europe stated that it recognised that self-regulation relied on companies providing a full and frank disclosure in response to any complaint to the PMCPA and that by failing to do so in Case AUTH/2747/1/15 Astellas failed to maintain high standards, contrary to the requirements of Clause 9.1. In addition, the company acknowledged that its provision of an incomplete response to the previous case, although unintentional, had regrettably brought the industry into disrepute, in breach of Clause 2.

Astellas Europe recognised that all the UK nominations had been received before the corrective email of 12 December, however, as noted above, at the teleconference preceding the email of 12 December all affiliates were asked, in the light of the revised selection criteria, to reassess whether the health professionals already nominated were appropriate. Again, as noted above, none of the affiliates requested any changes to those originally nominated. Astellas Europe relied on the compliance reviewers in each of the affiliates to make this decision.

Given what Astellas Europe now understood in relation to the comments made by Astellas UK during the nomination process, it acknowledged that high standards had not been maintained, contrary to Clause 9.1. In addition, Astellas Europe noted that during the Appeal Board consideration of the report to the Appeal Board from the Panel in relation to Case AUTH/2747/1/15 Astellas was asked whether there was any sales force involvement in the nomination process; its response was that there was not. Although Astellas believed at the time that this was so, it acknowledged that this constituted the provision of inaccurate information to the Appeal Board and was likely to be considered to be an action that might bring the industry into disrepute.

In relation to the approval process for this advisory board, Astellas Europe pointed out that the Panel would have noted that the final certification of the meeting did not take place until the day before the meeting took place, after health professionals had been selected and invitations had been sent. Astellas Europe acknowledged that this might constitute a failure to maintain high standards. In addition, the medical signatory to one of the items in relation to the advisory board (the 'save the date' card) was not at the time registered with the GMC due to administrative reasons, or any equivalent non-UK organisation. The individual was however 'registerable' and had since re-registered with the GMC. The signatory was no longer a member of staff. The Panel might consider the fact that a medical signatory was not suitably registered at the time of certifying an item to amount to a failure to maintain high standards, in breach of Clause 9.1.

### **Alleged dismissive manner in relation to Case AUTH/2747/1/15**

The complainant referred to attending training provided in relation to Case AUTH/2747/1/15 and that at a 'town hall' meeting, a very senior employee of Astellas discussed the case in a 'dismissive manner'. Astellas submitted that the company and the very senior employee personally, took the rulings in this case very seriously. Astellas stated that Healthcare Compliance (HCC) ran numerous compulsory training sessions for staff on the details of the case and the learnings taken from it. This training also included details on the requirements of advisory boards in general (a table was provided showing fifteen training dates and number of attendees at each session (total two hundred and five including seven agency staff)). All attendees were required to complete a mandatory validation quiz which was circulated via email. A copy of this training and validation quiz were provided. As Astellas Europe did not have a sales force, and given that the material was developed by HCC, members of which had detailed knowledge of the case and the wider Code requirements, Astellas Europe did not consider that the training required certification. It was, however, reviewed by legal, compliance and oncology colleagues before use.

For those who did not attend any of the sessions the training material was emailed to them with instruction to familiarise themselves with the content of the presentation and sample materials and complete a 'Read & Understood' form as well as the training validation quiz.

In addition, to ensure that employees fully understood the requirements in relation to advisory boards, a guidance document and tool kit had been developed and was sent to relevant Astellas Europe staff, and in June 2015 a moratorium on Astellas Europe advisory boards was put in place until September 2015 to allow staff to fully understand the Code and Astellas Europe's requirements in relation to such meetings. A copy of the email communication to staff in relation to this was provided.

Astellas Europe stated that there was one town hall meeting since Astellas received the complaint in Case AUTH/2747/1/15 where the very senior employee was in attendance, held on 15 May 2015. The slides used at this meeting were provided. This meeting was specifically to discuss EMEA vision and strategy. Astellas submitted that it could be seen from the slides that Case AUTH/2747/1/15 was not discussed. In addition, there was an Astellas UK 'town hall' meeting, on 14 April 2015, at which the very senior employee of Astellas Europe presented. Astellas Europe submitted that from the content, the case was not discussed.

However, in addition to the above training dates on advisory boards, Astellas stated that there were a number of occasions when the case and the rulings (both at the Panel and Appeal Board level) were discussed:

- Three Astellas Europe Quarterly Update Meetings took place in April 2015 with 28, 17 and 35 attendees, respectively. These were regular meetings at which recent Code cases were discussed. The invited audience was cross functional including legal, healthcare compliance, medical and marketing. At the meetings in April, the details of Case AUTH/2747/1/15 and the Panel ruling were communicated and discussed. The slides used at these three meetings and those disseminated to attendees and non-attendees were provided. The very senior employee attended one of the meetings and verbally summarised at the end of the session on the Panel's ruling.
- There were a number of briefing emails sent to Astellas Europe and affiliate staff in relation to the case and details of seven sent between April and July were provided. Astellas Europe submitted that it could be seen that all of the emails in relation to the case rulings and key learnings were from the Astellas Europe leadership team, and all emphasised Astellas' commitment to compliance and the importance of employees taking personal responsibility for this.

There were also a number of teleconferences in relation to the outcome of Case AUTH/2747/1/15 as below:

- Teleconference held on 5 May led by a senior employee, legal and compliance and attended by affiliate legal and compliance staff. The draft email to be sent to EMEA affiliates on 7 May was used as a script.
- Teleconference held on 6 May led by a senior employee, medical affairs and attended by affiliate medical directors and Astellas Operations medical directors. A script was used based on the draft 7 May email to EMEA affiliates.
- Teleconference held on 6 May 2015 led by a very senior employee of Astellas Europe and attended by the affiliate general managers. A script was used based on the draft 7 May email to EMEA affiliates.

In addition, four training sessions (for ninety-two attendees) were carried out in January-March 2015 in relation to a number of new and revised regional healthcare compliance standard operating procedures (SOPs).

In addition to the above training, all relevant staff also received the policies and processes through the Astellas electronic learning management system (LMS).

The very senior employee stated it was difficult to understand how he could be considered to have been dismissive of the outcomes of Case AUTH/2747/1/15. However, the complainant should have sought out the employee to clarify. This very senior employee had an 'open door' approach to receiving all feedback which was highlighted in all employee surveys. In view of the immediate steps taken to raise the awareness of all EMEA employees regarding the rulings in this case, including: mandatory advisory board training; advisory board moratorium and conference calls with all affiliate general managers, medical directors and legal/compliance staff, the very senior employee submitted that this demonstrated his commitment to compliance as opposed to any evidence of dismissiveness.

Since receiving this complaint, a number of Astellas Europe staff conducted interviews anonymously with individual members of staff that attended some of the training detailed above. In total, 12 members of staff were interviewed.

Astellas Europe submitted that nine of those interviewed considered that the individual took the matter seriously and did not discuss the case in a dismissive manner, as suggested by the complainant; two of those considered that he could have treated the matter more seriously. Three further members of staff considered that he was dismissive when discussing the case and the Panel's rulings.

Phrases used by those who considered that he was not dismissive were 'valuable [name] was there'; 'supportive'; 'not underplayed in any way'.

Other phrases recalled were 'we were trying something different'; 'the ruling shouldn't paralyse creativity'; 'there are large grey areas in application of the Code' and 'we don't want to stifle innovation'. Some of those who recalled these phrases were amongst those who did not consider that he was dismissive and some were amongst those who considered that the very senior employee should have taken the matter more seriously, which was an indication of the importance of perception vs intention in this matter.

Astellas Europe submitted that the above provided comprehensive detail in relation to the internal communications and training that was carried out to educate staff on the outcome and learnings from Case AUTH/2747/1/15 and the very senior employee's personal involvement with, and commitment to, this. Although there might be some comments to suggest that some staff interpreted a discussion in relation to this case as dismissive, this was certainly not his intention, and indeed other members of staff took the same comments in a positive way, and therefore the individual concerned did not consider that there had been a breach in that regard.

In response to a request for further information Astellas Europe acknowledged that the suggested criteria in the presentation of February 2013 and the criteria provided in the email of 5 September 2013 and the email to Astellas UK on 17 October 2013 were wholly inappropriate. Astellas Europe did not include the initial, unapproved, criteria in its response to the complaint in Case AUTH/2747/1/15 as these were not the ultimate final criteria communicated to the affiliates to identify health professionals that they considered should attend the advisory board.



Astellas Europe stated that whilst its response of 23 July 2015 might suggest that there was a conscious decision not to include reference to the emails and presentation, this was not the intention and the wording could have been clearer. At no point during the preparation of its response to Case AUTH/2747/1/15 was there a discussion as to whether the emails of 5 September and 17 October 2013 or the presentation of February 2013 should or should not be submitted; these were not considered at all. The focus of the reply concerned the arrangements for the meeting, the number of attendees and the nature of the meeting, ie, whether it was promotional or non-promotional rather than primarily the criteria by which attendees were selected. Astellas Europe acknowledged that its investigation into this complaint was wholly inadequate in that regard.

When responding to Case AUTH/2747/1/15, Astellas considered the arrangements for the meeting and addressed the questions raised by the Case Preparation Manager. It considered that the rationale for choosing the attendees was addressed in the meeting approval form which was retrieved from the approval system. Astellas Europe stated it was regrettable that the emails of 5 September and 17 October 2013, as well as the presentation from February 2013, were not included in the response to this complaint which was incomplete. Astellas Europe submitted this was unintentional as it never set out to deliberately mislead. Astellas Europe focused on the materials within the ZINC system, but now recognised that it should have asked the agency and other Astellas staff involved if they had records of any relevant emails or materials and it was regrettable that this was not raised.

In November 2013, concerns were raised internally about the advisory board. Further discussions took place and a decision was taken to issue a corrective email to address the inappropriate criteria previously communicated to the affiliates and to change the working groups from international sessions to national working group sessions at the meeting. The corrective email was not, however, sent in November 2013 but was sent after the WebEx in December which was held with all affiliates participating in the advisory board and two emails sent on 12 December 2013. The emails were as follows:

- 1 One corrective email giving further details on the participants at the meeting in that they should be '... nominated for their expertise in the management of prostate cancer'. This attempted, in good faith, to correct and finalise the selection criteria for the invited health professionals; and
- 2 A further email dated 12 December which referred to the compliance implications in changing from international working group sessions to national working group sessions. The reference to compliance was also in relation to the revised criteria provided in the first email of 12 December, as during the WebEx affiliates were asked to reconsider those health professionals that had already been nominated, based on the revised criteria. No further information was documented with regard to this request and, as noted previously, no affiliates changed the health professionals they had nominated. Astellas submitted that it had a legitimate expectation that such corrective criteria would be implemented locally as per local affiliate approval processes.

Astellas Europe stated that discussions were held initially with Astellas UK when the original complaint letter, dated 15 January 2015, was received by Astellas UK. As the complaint related to the arrangements for an Astellas Europe-led meeting the UK affiliate and Astellas Europe had a joint meeting to discuss the complaint and which organisation should respond. The decision was that Astellas Europe should respond to the complaint and an email was sent to the Case Preparation Manager to that effect.

After this time, an interim member of staff at the UK affiliate at the time of receipt of the complaint was involved in preparing Astellas Europe's response to Case AUTH/2747/1/15, but this was only because at the time of the meeting he/she had a role at Astellas Europe.

From the recollection of Astellas UK and Astellas Europe staff in relation to any further UK involvement, there was a meeting when the draft response to the complaint was being finalised in which a UK medical employee recalled being asked to review the written criteria that Astellas Europe planned to submit in its response (ie that the health professionals selected worked in the field of mCRPC and had personal experience of treating patients with mCRPC) and confirm whether these were the criteria used by the UK. This was confirmed from memory.

Again at this point during the preparation of Astellas Europe's response to Case AUTH/2747/1/15 there was no discussion in relation to the email of 17 October 2013 sent by the agency to the Astellas UK senior employee and whether this should or should not be sent in the response; this was not raised or discussed at all and this might have been due to the significant time that had elapsed since the email was sent meaning that those preparing the letter of response had no awareness of or had simply forgotten about the existence of the email.

The UK health professionals who attended the advisory board were nominated in response to the email of 21 October 2013 from the UK senior employee, of which five UK health professionals in total attended, details were provided.

A business update was provided by the very senior employee of Astellas Europe to the UK town hall meeting in April. No discussion was held in relation to Case AUTH/2747/1/15 at this meeting.

The town hall meeting in May was to enable a senior employee from the Japanese Headquarters to present the new corporate global vision of Astellas. No discussion was held in relation to Case AUTH/2747/1/15 at this town hall meeting.

Four individuals held interviews either face to face or over the telephone with 12 employees from Astellas Europe who had been present at the meetings where the very senior employee of Astellas Europe had spoken about the complaint and the Panel's ruling. These individuals briefed the interviewees on the second complaint and asked them to recall whether this individual made any comments in relation to Case AUTH/2747/1/15 and, if they did, specifically whether their recollection was that these comments were dismissive in relation to the rulings. They were also asked if they had any positive remarks to make in relation to any comments made when discussing the case. The guide used by interviewers was provided.

Due to the nature of the interview and the questions being asked, each interviewee was reassured that his/her comments would remain anonymous to the very senior employee and for this reason there was no formal report of each interview as such. Records were created following the interviews, and a collation was provided.

Astellas Europe stressed that while it now realised that the previous response was incomplete, there was never at any time any intention to be dishonest. Assumptions were made and subsequently proved to be incorrect. Astellas Europe reminded the Panel of the difficulty of recalling complex details a considerable time after the preparations for the Milan meeting.

## **PANEL RULING**

The Panel noted that the complainant was anonymous and non-contactable. As stated in the introduction to the Constitution and Procedure such complaints were accepted and like all complaints, judged on the evidence provided by the parties. Complainants had the burden of proving their complaint on the balance of probabilities.

The Panel considered this case under the 2015 Code.

The Panel noted the outcome of Case AUTH/2747/1/15 and that the Panel had ruled Astellas Europe in breach of Clauses 2, 9.1, 12.1, 18.1 and 20.1 in relation to arrangements for a meeting. The Panel had also reported the company to the Code of Practice Appeal Board. The Panel's rulings were not appealed. The company attended for the consideration of the report. The Appeal Board required Astellas Europe to issue a corrective statement to UK attendees. This was issued on 1 July 2015.

The Panel noted that a further anonymous complaint had been made about the meeting at issue. It was not known whether the complainant was the same as for Case AUTH/2747/1/15.

The Panel noted that the meeting at issue in Case AUTH/2747/1/15 had been run by Astellas Europe. The complaint concerned arrangements for UK attendees. In this regard the Panel noted that Astellas UK was responsible for the acts/omissions of its affiliates including its UK based European headquarters. In the Panel's view this remained the position even if the UK based European affiliate had responded directly to the complaint. In its response to Case AUTH/2780/7/15 Astellas Europe explained that on receipt of the complaint in Case AUTH/2747/1/15 a joint meeting of Astellas UK and Astellas Europe had decided that the European affiliate should respond to the complaint. Correspondence in relation to Cases AUTH/2747/1/15 and AUTH/2780/7/15 had consequently been sent directly to Astellas Europe. The Panel noted the company's submission about the involvement of the UK company with the response to Case AUTH/2747/1/15 prepared by Astellas Europe. The Panel noted the position of Astellas UK in relation to the present complaint remained as set out above.

The Panel noted that the criteria used to select advisory board members to attend the meeting in question must stand up to scrutiny and relate solely to their ability to provide expertise to the company. The Panel considered that the email from the agency for Astellas Europe to send to certain affiliates dated 4 September 2013, the email from the agency to the Astellas Turkey affiliate dated 5 September 2013 and the email sent from the agency to the UK senior employee dated 17 October 2013 were wholly unacceptable in relation to the criteria to be used to identify potential advisory board members. All the emails and/or their attachments listed above referred to invitees being mid to top level product opinion leaders with the potential to be local product champions within the relevant market and data-naïve customers ie those who had not been involved in any Astellas Europe or national/local advisory board meetings prior to the Pan EU Expert Meeting.

The presentation to the Oncology Steering Committee (5 February 2013) which accompanied the email of 4 September 2013 [Following notification of the Panel's rulings, Astellas Europe stated on 28 August that this was not so] referred to the success of the Pan – European Uro-oncology Advisory Board held in Barcelona in November 2012. It stated that the proposed structure of future meetings was discussed/agreed by a UK medical employee. This presentation referred to the aims and suggested target audience for 13/14 pan European advisory board meetings as:

### **'Objectives for meeting**

- Increase Astellas' profile in the field of oncology
- Communicate Astellas' strategy and oncology pipeline to key target customers
- Communicate Xtandi and tivozanib data and common set of messages to EU affiliates' key target customers
- Gain an increased understanding of the current landscape in RCC and prostate cancer & the challenges Astellas will face when launching Xtandi and tivozanib in the EU

### **Target audience for meeting**

- Mid – top level product OLs – those with the potential to be local product champions within the relevant EU markets
- Data – naïve customers, ie those who have not been involved in any APEL or national/local advisory board meetings prior to the pan EU ad board meeting
- 10 per affiliate: 5 prostate/Xtandi and 5 RCC/tivozanib\*

\*Turkey – 10CRPC OLs.'

The emails sent to the UK affiliate which reflected the selection criteria set out above, the email which the UK senior employee forwarded to UK managers, and the responses from this team dated 17, 21, 22 and 24 October compounded the unacceptability of the arrangements. In that regard the Panel noted the email from one of Astellas UK staff identifying health professionals who met these unacceptable criteria included '[city] is one of ... main key accounts', '...one of our high users and would respond well to such a meeting...', '... is influential at a [city] level and more and more nationally with time' and 'This is a business move ... barely sees industry, not using prechemo abi and once using he rarely changes'. The reserve nominations included '... I believe he has the reputation with us for being an abi man, however, this would give us the opportunity to convert him to the new way and '...is on our list and is influential, and would be good to engage at this level'.

The Panel did not accept Astellas Europe's submission in its initial response in the case now under consideration that its provision of an incomplete and in the Panel's view misleading response was unintentional given Astellas' decision not to include the unapproved criteria following the dispatch of what Astellas Europe described as a revised corrective email (December 2013). The Panel noted Astellas Europe's submission that it did not include the initial unapproved criteria in its response to Case AUTH/2747/1/15 as these were not the ultimate final criteria communicated to affiliates. It further noted the company's submission that there was no consideration at all as to whether the emails of 5 September and 17 October should be submitted as part of its response to the previous case, Case AUTH/2747/1/15. Astellas Europe acknowledged that its investigation into that complaint was inadequate.

The Panel was extremely concerned that Astellas Europe appeared to consider that ultimate revised final selection criteria had been communicated. In the Panel's view that was not so. Neither of the two emails dated 12 December sent from Astellas Europe contained revised selection criteria. That sent at 16.35, 'subject: Pan Eu expert meeting' discussed the meeting in relation to its objectives, content, format, timing and location. The Panel considered that the email described, *inter alia*, what the selected participants were expected to do. It did not make it at all clear that the original selection criteria had changed. Similar criticisms applied to the email

sent at 16.41. Contrary to the impression given by Astellas Europe this email referred only to compliance in relation to the change from international working group to national working group. The final paragraph asked affiliates to discuss the meeting with the compliance/Zinc manager. However again this paragraph did not refer to selection criteria revised or otherwise and within the context of the letter appeared to refer to the change to the international working group highlighted in the email. The Panel noted Astellas Europe's submission that the teleconference held on 12 December discussed the revised selection criteria for attendees. In the Panel's view this should have been made abundantly clear in the emails of 12 December. Astellas had not provided detailed information regarding the discussion on the teleconference. Given its comments above the Panel was not at all surprised by Astellas Europe's submission that none of its affiliates had subsequently requested any changes to those nominated as attendees. It was hard to understand why such a fundamental change to the selection criteria had not been made clear at the outset in either of the emails.

The Panel noted that the original selection criteria as set out in the emails of 4, 5 September and 17 October and the presentation to the Oncology Steering Committee dated 5 February 2013 were directly relevant to the subject matter of the complaint in Case AUTH/2747/1/15. In the Panel's view Astellas Europe had therefore provided not only an incomplete response to that complaint but also a misleading one.

The Panel noted Astellas Europe's submission that the final certification did not take place until the day before the meeting took place (26 February 2014) after health professionals had been selected and invitations sent.

In addition to the provision of an incomplete response, the Panel noted Astellas' submission that it was now apparent that its representatives had misled the Appeal Board when the report was considered as the UK sales force had been involved in the nomination process.

The Panel noted Astellas Europe's submission that concerns had been raised in November 2013 and that in January 2014 it had received an anonymous complaint about the meeting which had been dealt with by the issuing of the revised selection criteria and thus no further action was taken. The Panel noted its comments above about the revised selection criteria and their communication. The Panel also noted that Astellas Europe's response to the Panel's request for further information was different to its initial submission in relation to whether the company knew about the emails and the changes to the selection criteria for attendees and had decided not to provide them or whether the company had not asked staff for materials etc other than those in the Zinc system. In the Panel's view Astellas had either not paid sufficient attention to ensuring that all relevant information had been supplied in its response to Case AUTH/2747/1/15 or had made a conscious decision to omit relevant details from that response. The Panel noted Astellas Europe's most recent submission in this regard that it had not considered the material at all.

The Panel was extremely concerned and disappointed by the conduct of Astellas Europe and Astellas UK. The integrity of self-regulation relied upon the provision of complete and accurate information by pharmaceutical companies. The Panel considered that the failure to provide all the information and the misleading nature of what was submitted by Astellas Europe in Case AUTH/2747/1/15 meant that high standards had not been maintained. A breach of Clause 9.1 was ruled as acknowledged by Astellas Europe. The circumstances brought discredit upon and reduced confidence in the pharmaceutical industry. The Panel ruled a breach of Clause 2 as acknowledged by Astellas Europe. Clause 2 was a sign of particular censure.

In relation to the allegations about the discussion of the case by a very senior employee of Astellas Europe, the Panel noted the comments made by staff interviewed about meetings which the individual had attended. It appeared that these were not 'Astellas town hall' meetings as stated by the complainant. It was not clear what the meeting referred to by the complainant was but the complaint was clear it was a meeting where the very senior employee discussed the matter. The Panel was concerned that the interview guide for discussion with employees appeared to be biased and designed to encourage staff to confirm that they were impressed by the training and the 'Tone from the top'. Bearing in mind the difficulties for staff in being critical of senior management, the Panel was very concerned that the comments on the outcome of Case AUTH/2747/1/15 were viewed as dismissive and/or that the matter was not taken seriously enough. This was compounded by the serious nature of that case. The details set out in the collated interview feedback master document appeared to be different to those provided elsewhere in the company's response. Nonetheless it was clear that despite the content and tone of the interview guide, certain staff were concerned about the impression given. The Panel was also concerned that staff recalled the phrases 'we were trying something different' and 'there are large grey areas in application of the code'. The Panel disagreed with the latter comment in relation to Case AUTH/2747/1/15 as the requirements for advisory boards and other such meetings were clear in the Code, supplementary information and guidance issued by the PMCPA.

The Panel considered, given the seriousness of Case AUTH/2747/1/15, it was completely unacceptable in the companies' discussion of that case for a very senior employee of Astellas Europe to give any impression that he and/or the company was dismissive of the Panel's rulings and the Appeal Board's consideration of the report from the Panel. The Panel considered that in this regard high standards had not been maintained and ruled a breach of Clause 9.1. In addition the Panel considered that the circumstances brought discredit upon and reduced confidence in the pharmaceutical industry. The Panel ruled a breach of Clause 2. These rulings were appealed by Astellas Europe.

The Panel considered that the circumstances regarding the failure to provide comprehensive, accurate information, the misleading nature of the submissions in Case AUTH/2747/1/15, the relevance of the omitted material and the discussion of the outcome of the case by Astellas Europe raised serious concerns about the companies' procedures. In this regard the Panel noted Astellas Europe's submission about its certification of the arrangements the day before the meeting in question. It also noted the Appeal Board's comments when considering the report from the Panel in Case AUTH/2747/1/15 that the company's standard operating procedures were either unclear or not followed and its questions over the rigour of Astellas Europe's certification process. This case also raised fundamental concerns regarding Astellas Europe and Astellas UK's approach to compliance and self-regulation.

The Panel noted its comments above regarding the position of Astellas UK and Astellas Europe in relation to this case. The Panel considered that its serious concerns warranted reporting Astellas Europe and Astellas UK to the Appeal Board under Paragraph 8.2 of the Constitution and Procedure for the Appeal Board to consider in relation to Paragraph 11.3 of the Constitution and Procedure.

During its consideration of this case the Panel noted the meeting at issue was the third such meeting held by Astellas Europe. There had been no complaint about the previous two meetings which had taken place before and immediately after the initial marketing authorization of Xtandi in the treatment of adult men with metastatic castration-resistant prostate cancer whose disease had progressed on or after docetaxel therapy. The third meeting, the one at

issue in Case AUTH/2747/1/15, was held prior to the grant of the marketing authorization for a new indication for the treatment of adult men with metastatic castration-resistant prostate cancer who were asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy was not yet clinically indicated. On the basis of the new information which came to light in Case AUTH/2780/7/15 the Panel was concerned about the arrangements for the two previous meetings held in 2012 and 2013 and the company's response to Case AUTH/2747/1/15. However there was no complaint about these two meetings, either in this case or the previous case. The Panel requested that Astellas be advised of its views.

### **APPEAL BY ASTELLAS EUROPE**

Astellas Europe appealed the Panel's rulings of breaches of Clauses 9.1 and 2 in relation to the allegation that a very senior employee had discussed the Panel ruling in Case AUTH/2747/1/15 in a dismissive manner.

Astellas Europe noted in its response to the complaint there were a number of occasions where this individual was present when Case AUTH/2747/1/15 was discussed; each meeting was different in relation to the number of attendees, audience, format and his personal role and involvement. There were a number of key points that should be taken into consideration as detailed below.

Astellas Europe noted that the complainant alleged that a very senior employee had discussed Case AUTH/2747/1/15 in 'a very dismissive manner'. One definition of 'dismissive' was: 'contemptuous, scornful, disdainful, insulting, sneering, derisive; He was highly dismissive of the report'. The Oxford English Dictionary noted that dismissive as an adjective was defined as 'showing that you feel something is not worth consideration'. These were strong terms which could also be subjective. None of these words were used by any of the Astellas Europe staff who were interviewed during its preparation of its response to Case AUTH/2780/7/15.

Astellas submitted that 'Tone from the Top' was critical in any compliant organisation and it was an aggregate of continuous, transparent and consistent activities, policies and procedures, communications in various forms and formats, oversight by a governance structure (consisting of the head of the organisation and a senior cross-functional management team), auditing and monitoring and responding to deviations and enforcement of standards. Critical to this was the importance of engagement of senior leadership in demonstrating an organisation's approach to compliance. 'Tone from the Top' was not defined as a single activity, communication or conversation. The individual concerned took a very structured approach to this in leading an organisation of approximately 4,000 employees across the regions of Europe, Middle East and Africa as well as a very senior role at Astellas Pharma Europe Operations. Astellas Pharma Europe Operations consisted of approximately 350 employees (encompassing 32 nationalities) and approximately one quarter did not have English as their first language. Therefore, in communicating important messages, various channels were used eg, email, face-to-face and teleconferences. These communications were carefully prepared to ensure a consistent message. It was in this context that the alleged comments must be considered.

Astellas Europe noted that the individual had adapted his communication style to take into consideration the audience, including both non-native and native English speakers and he therefore tended to be very factual and even-tempered. This might create varying nuances and interpretations with both native and non-native English speakers. Perhaps the complainant was expecting him to exude more 'fire and brimstone' in relation to the circumstances and rulings in Case AUTH/2747/1/15. The individual did not consider this appropriate as he had simply

wanted to convey to the audience in each of his communications the fact that Astellas had got it wrong, the seriousness of the case and the necessary 'lessons learned'. Finally, he conveyed the need to fix the problem and move forward in a compliant manner; he wanted staff to understand that if they learnt from mistakes they could confidently make the compliance decisions they needed to make on a day-to-day basis.

Astellas Europe submitted that the individual concerned had been highly engaged in all of the communication activities around Case AUTH/2747/1/15, which took place with his strong and open support (as previously stated and shown below). If any individual took as dismissive any of his comments, this should be seen as a misunderstanding. As an aggregate, the various communications and activities that took place in relation to the rulings in the case demonstrated strong leadership and personal support for Astellas Europe's positive approach and attitude to healthcare compliance. The very senior employee also held a town hall meeting that took place for Astellas Pharma Europe and UK staff on 30 July where both cases were referred to (slides with notes were provided):

<b>Activity</b>	<b>Date</b>
Advisory Board training (15 sessions)	5 May-12 June 2015
Astellas Pharma Europe Quarterly Compliance Update (3 sessions)	8, 15 and 22 April
Panel ruling communication	8 April 2015
Key Learnings teleconferences (3 sessions)	5 and 6 May 2015
Key Learnings communications (emails to Astellas Pharma Europe and the UK Affiliate and to EMEA affiliates)	7 May 2015
Appeal Board ruling communications (emails to Astellas Pharma Europe and the UK Affiliate and to EMEA affiliates)	28 May 2015
Communication on the Advisory Board Moratorium	2 June 2015
Communication on the publication of the case report (emails to Astellas Pharma Europe and the UK Affiliate and to EMEA affiliates)	1 July 2015
Communication on the issue of the Advisory Board Tool Kit	1 July 2015
Astellas Pharma Europe and UK Affiliate town hall	30 July 2015

Astellas Europe discussed the meetings at which some of those interviewed considered that the very senior employee had been dismissive (the Quarterly Compliance Update and the Advisory Board training). At these meetings, rather than leading them, the individual attended in person as a trainee.



At the Quarterly Compliance Update meeting in April 2015, Astellas Europe submitted that the individual concerned recalled, at the end of the meeting, discussing with all the attendees that one key aspect of the case was that Astellas had failed to establish the Milan meeting as non-promotional, and that the other issues such as unacceptable payments flowed from that finding. This discussion was not intended to be dismissive of the Panel's ruling. The individual was merely trying to convey the concept that if you got this aspect wrong then all of the other arrangements and details were likely to be inappropriate. He reminded attendees that although they worked in an environment that required creativity and innovation, this must be done in a compliant manner, and referred specifically to the Panel ruling in that holding multiple simultaneous local advisory boards overseas in one central location was not necessarily unacceptable, but the 'devil was in the detail' and the execution and content must be compliant. The individual then opened the floor to any questions and reiterated what was said on the slides presented at the meeting, that further information would be provided during the compulsory training on advisory boards. The relevant slides were provided.

Astellas Europe submitted that in the advisory board training meeting held in June 2015, there were four attendees and the trainer; two of the attendees had only recently joined the organisation and this was the first time that the very senior employee had interacted with these two individuals. The training session was specifically designed to be interactive to enable the trainees to ask questions for clarity in order to improve future planning and execution of advisory boards. During this training, which referred to the aspects of the case, the very senior employee raised questions with the trainer on the detailed learnings of the rulings, especially that the Q&A section of the advisory board was not considered part of the advice gathering aspect of the meeting. The very senior employee was not dismissive, to the contrary, he was trying to understand the ruling in order that he could apply the learnings. Once again, the same key aspect was discussed ie, the failure to establish the meeting as non-promotional and the issues flowing out of this. The tone and manner when the very senior employee was speaking at this meeting was that of a trainee rather than as one leading the meeting.

The Panel had noted the very senior employee's comment that 'there are large grey areas in the application of the Code' and disagreed with this comment in relation to advisory boards. Astellas Europe submitted that this comment was not made in relation to advisory boards nor the specific case being discussed. Astellas fully agreed that the requirements for advisory boards were very clear in the Code, as well as supplementary information and guidance issued by the Authority. However, this comment was made in relation to the Code in general as the new Code had been published for 2015 and was due to come into full effect around the time of communicating the learnings from Case AUTH/2747/1/15. As this was discussed in a learning environment, the very senior employee encouraged his colleagues to question any areas of the Code that they did not understand and seek advice, if necessary.

Astellas Europe trusted that it had put into context any misunderstanding that might have arisen in relation to the discussion of the rulings in Case AUTH/2747/1/15 and its wider approach to healthcare compliance. The concerns of individuals about whether the very senior employee was dismissive or could have taken the rulings more seriously perhaps were more of a disconnect between communication style/delivery and that which the individual might have expected given the subject matter. Taken as a whole, the volume of communication and training that took place following the Panel's and Appeal Board's ruling in relation to this case, as opposed to an alleged isolated comment that appeared to have been misconstrued, demonstrated the very senior employee's commitment to, and leadership in, compliance with the Code, and thus Astellas Europe submitted that that there had been no breach of Clauses 9.1 or 2 in that regard.

Finally Astellas Europe submitted that the 'Tone from the Top' the very senior employee had set for the company had been one of personal engagement, support, transparency and strong leadership to ensure employees understood the importance of healthcare compliance. At the Appeal Board meeting, in addition to providing a short presentation in relation to its appeal, Astellas Europe would also provide the Appeal Board with information on the key compliance activities that had been and were taking place since the conclusion of Case AUTH/2747/1/15.

## APPEAL BOARD RULING

The Appeal Board noted that the appeal related to the complainant's view that a very senior employee of Astellas Europe discussed the outcome of Case AUTH/2747/1/15, in a very dismissive manner.

The Appeal Board noted that the interview guide used for staff who had attended a meeting with the very senior employee stated 'From my recollection of that [telecom] [meeting] I was not aware of any dismissive comment(s) ...'. It then stated 'In fact [I was impressed] by the mandatory training and "Tone from the Top" reflecting the importance of compliance at Astellas'. The Appeal Board considered that the interview guide was biased. The Appeal Board noted the response from the Astellas representatives at the appeal that the interview guide was used by interviewer to 'get the conversation started'. However, the Appeal Board queried whether this was so given that it requested a 'Name', 'Title' and included a signature clause at the bottom. In the Appeal Board's view, given the content of the interview guide and that the interviews were overseen by a senior director the interviewees would be left in no doubt what was expected of them. The Appeal Board noted that despite the strong steer of the guide some interviewees still considered a more cautionary tone might have been conveyed, one expressed surprise that the ruling was not being treated seriously. One interviewee used the word 'belittled'. One considered that the very senior employee was dismissive, referred to the breaches as technicalities and when referring to the breaches stated that the organisation of the advisory board was not non compliant but rather its execution. At the Appeal Board hearing the individual was very clear that he had not used the word 'technicality'. The Appeal Board noted that in the collated interview feedback master document some interviewees had adopted phrases closely similar to those in the interview guide. The Appeal Board noted that it had only received collated interview responses from twelve employees and yet there was still evidence that the very senior employee had been dismissive or that the matter was not taken seriously enough. The Appeal Board also noted the company's submission that the individual attended the advisory board training as a trainee which was reflected in his tone and manner.

The Appeal Board considered that the communications concerning the outcome of Case AUTH/2747/1/15 did not unequivocally convey, as submitted by Astellas Europe in that case, that it had agreed that the execution of the Pan-European Advisory Board should have been conducted to a higher standard and it did not meet the criteria for advisory boards, as required by the Code and its standard operating procedures (SOPs). The Appeal Board noted that to convey the seriousness of the matter to a broad audience it was important that such communications were abundantly clear. The Appeal Board was particularly concerned about the wording for the teleconference script used by the very senior employee which stated that 'Unfortunately, due to poor execution of the arrangements and materials, the *perception* of the meeting by the complainant and by the PMCPA (the UK code authority), was such that Astellas was ruled in breach of a number of clauses of the Code.' (emphasis added). The Appeal Board considered that 'perception' could be seen by some as ambiguous and implied that this was other than a clear breach of the Code.

The Appeal Board was concerned that staff recalled the phrases 'we were trying something different', 'the ruling shouldn't paralyse creativity' and 'there are large grey areas in application of the Code'. The representatives from Astellas at the appeal stated that these phrases had been used to relate to the Code in general and to raise discussion. The Appeal Board considered that for the very senior employee to make such comments when cascading the outcome of Case AUTH/2747/1/15 sent a confusing message. In that regard the Appeal Board noted that the requirements for advisory boards and other such meetings were clear in the Code, supplementary information and guidance issued by the PMCPA. The arrangements for Astellas Pan-European Advisory Board were unacceptable and clearly in breach of the Code and the company had accepted this. The company did not appear to have clearly explained the gravity and seriousness of the breaches, the report from the Panel to the Appeal Board and corrective statement in its communications.

The Appeal Board considered that on the balance of probabilities there was evidence to show that the very senior employee of Astellas Europe had given the impression that he was dismissive of the Panel's rulings and the Appeal Board's consideration of the report from the Panel. In this regard high standards had not been maintained and the Appeal Board upheld the Panel's ruling of a breach of Clause 9.1. The appeal on this point was unsuccessful.

The Appeal Board considered that the impression given brought discredit upon, and reduced confidence in, the pharmaceutical industry and it upheld the Panel's ruling of a breach of Clause 2. The appeal on this point was unsuccessful.

#### **COMMENTS FROM ASTELLAS EUROPE ON THE REPORT FROM THE PANEL**

Astellas Europe contacted the PMCPA in September to advise that it had recently discovered information which the company wished to provide to the Appeal Board in relation to its consideration of the report from the Panel. The Director of the PMCPA referred the matter to the Chairman of the Appeal Board who, agreed that Astellas Europe could submit further information in relation to the report. The information did not relate to Astellas UK.

Astellas Europe stated that it had conducted a number of staff interviews as part of its continued human resources investigation into the complaint and an email had been discovered which it considered to be the source of the concerns that were raised in November 2013 about the advisory board at issue in Case AUTH/2747/1/15. Astellas Europe referred specifically to the wording of its response to the complaint where it stated 'In November 2013, concerns were raised internally about the advisory board'.

Astellas Europe submitted that it was important for the Appeal Board to be made aware of the content of this email when it considered the report from the Panel in Case AUTH/2780/7/15. The email, from a senior employee at Astellas Europe was dated 26 October 2013 and indicated that the sender was instructing the team to remove an unacceptable objective for the advisory board from the meeting agenda in order to 'smooth the passage' of the meeting through the approval process, but unfortunately made it clear that this was still a key objective of the advisory board.

Astellas Europe noted that as background, an email entitled 'Draft agenda for the Feb Pan EU Advisory Board Meeting' was sent by its agency to various members of the oncology business unit on 24 October 2013 at 22:00. Attached to this email was a draft agenda for the meeting that was the subject of the complaint in Case AUTH/2474/1/15. On the same day, at 22:48, a

member of the oncology business unit replied with a revised agenda attached. The revised agenda contained tracked changes; the objective 'Communicate the role of uro-oncology as a major component of the Astellas Oncology strategy' had been crossed out, with the comment 'Should this really be an objective of an ad board?'.

The email of 26 October 2013 from the senior employee to the agency stated, *inter alia*:

'Re Objective about communicating our Oncology strategy, agree let's take off to smooth the passage through Zinc although be clear amongst us that communicating our commitment/strategy is a clear objective of this type of meeting which we will need to cover off as in the agenda.'

Astellas Europe submitted that this indicated that there was a conscious decision on the part of one individual to circumvent the established approval process in order to incorporate an unacceptable objective in to an advisory board ie to use the meeting to establish relationships with health professionals and communicate the company's strategy in a particular therapy area.

Astellas Europe submitted that the email appeared to be the trigger for the activities that took place in late 2013 to reassess the meeting and address the concerns raised. Two of the four members of staff in receipt of the email of 26 October 2013, whilst not sharing or discussing the email directly with anyone, raised their concerns about the meeting. The activities in November and December 2013 were as a consequence of this in an attempt to correct the issues raised eg the teleconference and emails of 12 December 2013.

Astellas Europe as an organisation stated that it was not aware of the emails until 22 September 2015 which was why they were not submitted in the company's response to Case AUTH/2780/7/15. This was particularly disappointing, given that the individual in question was asked for all information relevant to the meeting at issue in Case AUTH/2747/1/15. As a result of this discovery further investigations were on-going.

Astellas Europe stated that the Panel's ruling in Case AUTH/2780/7/15 might still have been the same, given that it recognised the inadequacies of the initial investigation to the complaint in Case AUTH/2747/1/15. However it was important that the Appeal Board was notified of the additional information, which the company submitted was crucial to the case.

At the consideration of the report the representatives from Astellas Europe and Astellas UK stated that the companies recognised that the investigation and response to Case AUTH/2747/1/15 was inadequate. The companies submitted that there was no dishonesty or deliberate attempt to mislead. The investigation had identified that an individual senior member of staff central to this situation withheld key information from Astellas Europe, the Panel and Appeal Board. Immediate action had been taken to address the conduct of this senior member of staff. Astellas incorrectly assumed that there was no sales involvement in nominating UK health professionals to attend the advisory board and therefore it unintentionally provided inaccurate information to the Appeal Board.

Astellas accepted the Panel's rulings of breaches of the Code and deeply regretted that it had brought disrepute on the pharmaceutical industry.

Astellas Europe stated that it had already undertaken a number of measures and gave details of its key compliance activities since the completion of Case AUTH/2747/1/15. These included: internal audit preparation; full gap analysis of healthcare compliance program by external

consultant at Astellas Europe; review and revision of existing standard operating procedures (SOPs) and policies, development of new SOPs including: Astellas Europe - Complaint Handling SOP and Deviations SOP, UK Affiliate – Advisory Board SOP, advisory board moratorium within Astellas Europe until 31 December 2015; all UK led advisory boards required medical director approval in addition to routine approvers, communication on publication of case report, communication on advisory board toolkit/templates within Astellas Europe; approval for further increase in healthcare compliance headcount; town hall meetings.

## **APPEAL BOARD CONSIDERATION OF THE REPORT FROM THE PANEL**

The Appeal Board noted the Panel's comments and rulings including its ruling of a breach of Clause 2 and the outcome of the appeal where the Appeal Board upheld a second Panel ruling of a breach of Clause 2. The Appeal Board was extremely concerned about the approach to compliance and poor communication across Astellas Europe and Astellas UK.

The Appeal Board noted the Panel's comments that the original selection criteria for Astellas Europe's Pan-European Uro-oncology Advisory Board Meeting were directly relevant to the subject matter of the complaint in Case AUTH/2747/1/15 yet these had not been provided by the company in its response to that case.

The Appeal Board was also very concerned about why the email dated 26 October 2013, sent by the senior employee of Astellas Europe was not previously provided. The Appeal Board noted from Astellas that two recipients of the email had raised concerns about the meeting back in 2013 but they had not disclosed the email itself. The representatives from Astellas at the consideration of the report stated that the email was handed to senior management by one or more employees on 22 September 2015. The Appeal Board was concerned that such relevant information had not surfaced until this late stage.

It appeared to the Appeal Board that employees did not feel confident to raise issues with management. It noted that the company had received an anonymous complaint but the company considered this had been dealt with. At least three senior members of staff could have raised their concerns and did not.

The Appeal Board was very concerned about the culture of the organisations and that despite a prior internal complaint raising the issue it had taken two complaints under the Code and a late submission of evidence in the present case to produce comprehensive information concerning selection of the delegates for the meeting at issue.

The Appeal Board was concerned that the arrangements had been reviewed and approved by the UK affiliate. Astellas Europe certified the arrangements the day before the advisory board at issue took place. The Appeal Board noted that there was no UK medical director at the relevant time and further that due to a number of relevant vacancies at Astellas Europe, the European company relied on the UK affiliate for guidance. '[Post meeting note: Subsequently, on notification of the Appeal Board ruling, Astellas advised that it did have a UK medical director in post at the relevant time]'.

The Appeal Board considered that Astellas had provided not only an incomplete response to the original complaint but also a misleading one. The Appeal Board considered that self-regulation relied upon the provision of complete and accurate information by pharmaceutical companies. Astellas's omission was totally unacceptable. The Appeal Board decided that in accordance

with Paragraph 11.3 of the Constitution and Procedure that both Astellas Pharma Europe and Astellas UK should be publicly reprimanded for this failure.

The Appeal Board noted that the UK health professionals who attended the meeting had been provided with a corrective statement and a case report which was misleading. This was totally unacceptable. Consequently the Appeal Board decided, in accordance with Paragraph 11.3 of the Constitution and Procedure, to require Astellas Europe and Astellas UK to issue a corrective statement to all the UK attendees at the meeting to clarify the position. The corrective statement should refer to both case reports. Under Paragraph 11.3 details of the proposed content and mode and timing of dissemination of the corrective statement must be provided to the Appeal Board for approval prior to use. [The corrective statement appears at the end of the report.]

The Appeal Board also decided that, given all of its concerns about the conduct of Astellas as set out above, to require, in accordance with Paragraph 11.3 of the Constitution and Procedure, an audit of both Astellas Pharma Europe and Astellas UK's procedures in relation to the Code. The audit would take place in December 2015. On receipt of the audit report, the Appeal Board would consider whether further sanctions were necessary including the possibility of reporting the companies to the ABPI Board of Management (Paragraph 12 of the Constitution and Procedure).

#### **APPEAL BOARD FURTHER CONSIDERATION**

Astellas Pharma Europe and Astellas UK were each audited in December 2015 and on receipt of the report of the audits, the Appeal Board noted that it included separate findings and recommendations for each company as well as joint findings and recommendations. The Appeal Board was extremely concerned that despite a very critical report that highlighted numerous serious concerns including the companies' cultures and a reference to Astellas Europe's institutional failure with respect to compliance, neither Astellas Europe nor Astellas UK provided any detail on when and how each would address those concerns.

The Appeal Board decided that both companies should be re-audited but before setting a date for such, each should provide a detailed compliance action plan and a comprehensive response to the recommendations in the report of the audits. The Appeal Board discussed further sanctions including, again, whether there should be a report to the ABPI Board. The Appeal Board concluded that on receipt of the report for the re-audits it would decide whether further sanctions were necessary.

In February 2016 the companies subsequently provided a further detailed response as requested. The Appeal Board considered that both companies had set themselves a number of compliance objectives and sufficient time would be needed for these to be completed or get underway. In that regard the Appeal Board decided that Astellas Pharma Europe and Astellas UK should each be re-audited in September 2016 by which time the Appeal Board expected both companies to be able to demonstrate significant improvement.

#### **CODE OF PRACTICE PANEL FURTHER CONSIDERATION**

During the Code of Practice Appeal Board's consideration of the audit reports for Astellas Europe and Astellas UK (25 February 2016) it noted a letter from Astellas Europe (17 February) which stated that new information had been discovered as a result of further investigation which would assist the understanding of the full circumstances of these cases. The company would

send the information to the PMCPA. The Appeal Board requested that the Director followed this up.

On receipt of further information from Astellas Europe the original Panel was reconvened to consider the matter.

## **FURTHER INFORMATION FROM ASTELLAS EUROPE**

Astellas Europe set out the organisational restructure in relation to compliance. A new function, Ethics & Compliance, with a global reporting structure, would be established effective from 1 April 2016. This was reflected at Astellas Europe by dividing 'Legal & Compliance' into 'Ethics & Compliance, EMEA' and 'Legal, EMEA'. The Ethics & Compliance function would report outside of Astellas Europe to Japan, thus providing a much more robust compliance structure with no reporting line in to senior management at Astellas Europe. Astellas was now recruiting a dedicated senior healthcare compliance director to report in to the Ethics & Compliance function.

Astellas Europe stated that Astellas Pharma Inc, with the assistance of external counsel, conducted a thorough internal investigation into the circumstances leading up to the meeting in Milan (Case AUTH/2747/1/15) as well as matters that led to Astellas Europe providing an incomplete and misleading response (Case AUTH/2780/7/15). The results of the completed investigation had been shared with Astellas. The majority of the report confirmed facts already known to the PMCPA and it revealed further information that appeared to have been known to a number of members of Astellas Europe senior management but had not, to date, been shared with the Authority. The details were provided below.

Astellas Europe was notified of the complaint in Case AUTH/2747/1/15 on 15 January 2015 and its initial response to this complaint was submitted to the PMCPA on 6 February 2015. The interviews conducted during the investigation, as well as a review of email accounts of certain individuals, had revealed that, on 30 January 2015, whilst the response to the PMCPA was being prepared, an email was sent by a member of the oncology business unit to his line manager. This email, *inter alia*, referred to the email of 5 September 2013 ('selection criteria email') sent by a senior employee to Astellas affiliate employees (the email that became the subject of the complaint in Case AUTH/2780/7/15) and expressed concern that the response to the PMCPA under preparation would not disclose the selection criteria email. The 30 January 2015 email referred to the need 'to provide the PMCPA with a full and truthful response to the complaint made and not to mislead or deceive them'.

The employee who received the 30 January email raised it with very senior employees all of whom were involved in drafting the response which stated, *inter alia*, that 'we have no intention to mislead or deceive and will provide an appropriate response to the PMCPA'. Astellas Europe considered that this demonstrated that the very senior employees quite clearly addressed the question of whether or not to include the original selection criteria for health professionals invited to attend the Milan meeting in the response to Case AUTH/2747/1/15 and deliberately decided to omit such information. This was, of course, wholly unacceptable.

A new President of Astellas, EMEA Operations, was appointed on 1 April 2016. Very senior managers had left the organisation.

Astellas Europe stated that it remained committed to continuing the significant changes that were required to address the issues leading to the audit in December 2015 and those noted

during that audit. It remained committed to operating with the highest sense of ethics and integrity.

Following a request from the PMCPA for further information which referred to the need to inform the Appeal Board of the position and that this might be by way of a report under Paragraph 8.2 of the Constitution and Procedure, Astellas Europe provided more information including the report by external counsel.

### **FURTHER INFORMATION FROM ASTELLAS EUROPE**

The investigation report, prepared by external counsel which was provided to the investigation committee of the Astellas Europe Board, contained privileged material, notably summaries of the content of interviews conducted with employees. All material information gathered in the course of these interviews was communicated within the findings.

In response to the PMCPA question as to how and when the email of 30 January 2015 was raised by an employee with senior management and how Astellas Europe knew this, the company stated that the investigation team learned from an interview with its employee that the email was brought by him/her into an impromptu meeting between him/her and senior employees.

During an interview with the investigation team, a very senior employee corroborated that the email had been discussed at this meeting and that, also at this meeting, he/she had typed the response to it. Astellas Europe understood that this very senior employee read the response out to the group as he/she typed it.

Some further documentation about the 30 January 2015 email was reviewed by the investigation team. It appeared that Astellas Europe's human resources department, did not understand the significance of the email.

In response to another request from the PMCPA, Astellas Europe stated that a number of staff including very senior staff had left the company.

Astellas Europe stated it was confident that, with the organisational restructure resulting in the creation of the Ethics & Compliance function, the new personnel in place and the action plans developed in response to the issues identified during the PMCPA audit, it would be able to address the PMCPA's concerns. Most critically, the new structure and the declared plan of actions would considerably strengthen Astellas Europe's compliance governance and oversight.

### **PANEL RULING**

The Panel noted the circumstances surrounding Cases AUTH/2747/1/15 and AUTH/2780/7/15, the reports to the Appeal Board, the findings of the audits, particularly those relevant to Astellas Europe, and the additional information now provided by Astellas Europe. The companies were to be re-audited in September 2016.

The Panel noted that the additional information was provided by, and concerned acts and omissions by, Astellas Europe. The Panel noted that Astellas Europe was not a member of the ABPI, although it was a member of EFPIA. Astellas UK was a member of the ABPI. The Panel had previously noted that Astellas UK was responsible for the acts/omissions of its affiliates that fell within the scope of the Code including its UK based European headquarters. The Panel had



previously stated that, in its view, this remained the position even if the UK based European affiliate had responded directly to the complaint. In the present matter, the Panel noted that the position of Astellas UK remained as set out above. The Panel also noted that Astellas Europe, as a consequence of its membership of EFPIA, agreed to be bound by the UK Code including any applicable sanctions. This was set out in various EFPIA codes.

The Panel noted all the concerns and comments it had raised previously. It was appalled at the conduct of senior managers as revealed in the additional information in relation to the two cases and resulting audits. Senior managers failed to provide full and accurate details to the Panel, the Appeal Board and the Authority in relation to the audits. Some very important details, although hinted at by the Panel, the Appeal Board and by the Authority in the report of the audits, had only come properly to light as a result of the follow-up investigation ordered by Astellas Japan and carried out by an external counsel. This might, in part, have been triggered by the audits including the conversation the PMCPA had with the CEO and President Astellas Group.

The report from external counsel stated that all those involved in compiling the information and drafting the response to Case AUTH/2747/1/15 were aware of the existence of the original selection criteria, as on 30 January 2015 senior employees' attention was drawn to the email which set out the original selection criteria. This was inconsistent with Astellas Europe's original response that material outside Zinc was not considered when drafting the response to the PMCPA.

The report from external counsel noted that the company's investigation following receipt of the second complaint (Case AUTH/2780/7/15) was inadequate. It failed to uncover the email of 26 October 2013 which stated that the commercial objective would be removed from the meeting agenda in order to 'smooth the passage' through Zinc but would remain an unwritten objective. The external counsel report noted that the failure to conduct a thorough fact-finding exercise at any time following the first PMCPA complaint was concerning and was even more troubling given the number of senior staff who knew exactly where to look for the relevant material.

The external counsel report stated that staff considered business concerns prevailed over compliance concerns and that there were no consequences for compliance breaches. Further, matters relating to the PMCPA investigation and the oncology business unit were kept within the management team and not shared with Japan. The concerns over integrity raised by the PMCPA in its report of the audits were amplified and confirmed by the external counsel findings.

The report from external counsel also acknowledged management failings and that the PMCPA criticisms of the Milan meeting were likely to apply to two other advisory board meetings which were described in the report as being similar. Mention was also made of the pressure of working in the business unit. Compliance concerns with regard to the Milan meeting were raised by the Nordic countries. The report by external counsel stated that the correction email (12 December 2013) was wholly inadequate to remedy the problems created by the promulgation of the original selection criteria.

The Panel considered that the additional information demonstrated that a number of individuals in Astellas Europe had not provided complete and accurate information. That this included very senior employees was extremely concerning. Astellas Europe's conduct was completely unacceptable. The report of the audits had found that there was an institutional failure with respect to compliance; a finding which, in the Panel's view, was now compounded by the additional information including the report by external counsel. The failings of Astellas Europe,

as demonstrated by the additional information, went beyond, and were arguably even more serious than, those outlined in the report of the audits. The latest information demonstrated that Astellas Europe staff had lied about the original selection criteria on a number of occasions and not limited to Astellas Europe's response to the complaints but including when interviewed individually by members of the Authority at the audit, when they appeared before the Appeal Board in relation to the reports from the Panel in both cases and at the appeal in Case AUTH/2780/7/15. The failure to provide accurate, complete information at an audit and to the Appeal Board was a very serious matter. The truthfulness and accuracy of such comments and submissions to the Authority was fundamental to the integrity of self-regulation. It was remarkable that the individuals concerned had not provided the correct information sooner despite having had every opportunity to do so; the true position only emerged after those from the PMCPA carrying out the audits had spoken to the Japanese parent company and a report from external counsel was commissioned. The Panel was also concerned about the newly revealed breadth of compliance failures such as flawed processes including human resources processes wherein vital compliance material was not recognized as such, and the apparently unfettered influence of the named senior individuals upon matters such as disciplinary investigations. The Panel noted that very senior employees had left Astellas Europe. The Panel decided that it would report Astellas Europe to the Appeal Board under Paragraph 8.2 of the Constitution and Procedure for it to consider in relation to Paragraphs 11.3 and 11.4 of the Constitution and Procedure. Astellas UK would be advised accordingly.

#### **COMMENTS FROM ASTELLAS EUROPE AND ASTELLAS UK ON THE REPORT FROM THE PANEL**

At the consideration of the report the representatives from Astellas Europe sincerely apologised for the significant cultural and compliance failings created and caused by the actions and behaviours of some of its very senior managers. Globally Astellas viewed the current position as a corporate crisis. The newly appointed President of Astellas Europe referred to his global experience with the company and stressed his commitment to improve corporate culture such that ethics and compliance were embedded throughout the organisation. Some of that cultural change would come through the appointment of new people into key roles.

In addition to Astellas Europe's compliance action plan submitted as part of its response to the audit recommendations, the company submitted it was improving its corporate culture with new SOPs and whistle blowing arrangements. The company's compliance function would no longer be managed locally but would report to the newly appointed Senior Vice President and Head of Ethics and Compliance who in turn reported to the global company. Senior leadership in medical affairs now reported globally and was no longer managed by Europe. Dedicated compliance professionals would also be employed at every European affiliate.

In response to questions the Astellas Europe representatives explained that the main culprits had left the company and further remaining members of staff were being given additional training. There had been adverse consequences for some staff at their annual appraisal. The new President of Astellas Europe was also currently acting as head of human resources (HR). A strong message had been given to the organisation about the seriousness of the situation. The seriousness of the situation had not previously been well communicated to Japan by Astellas Europe but following the PMCPA's interview of the Global CEO and President (as part of the December 2015 audits) immediate action was taken including an investigation undertaken with the assistance of external counsel.

The representatives from Astellas UK submitted that the company took its responsibilities under the Code very seriously. The UK General Manager reported to a position in the Netherlands which in turn reported to Astellas Europe. The UK company noted that very senior managers from Astellas Europe had colluded to deliberately mislead and not tell the truth. Such dishonesty was completely unexpected and was not at all known to the UK until it saw the report from external counsel which was provided as part of the report to the Appeal Board. The UK company was committed to working closer with Astellas Europe to clarify responsibilities and to ensure that the UK approved and certified any activity undertaken by its European affiliates that involved a UK health professional or took place in the UK. The company would also take responsibility for any future complaints under the Code about such activities. The UK company referred to ongoing compliance work including the seven work streams it had established to address findings from the audit.

[Post meeting note: Subsequently following the Appeal Board's consideration of the report in May 2016 Astellas stated that the internal investigation would have happened regardless of the PMCPA's interview of the Global CEO and President. The external counsel report, dated 24 March 2016 referred to an Astellas Europe Board resolution dated 20 January 2016 to investigate the matters described in the two cases including the PMCPA audit report].

#### **APPEAL BOARD CONSIDERATION OF THE REPORT FROM THE PANEL**

The Appeal Board welcomed the full apology made by the representatives of Astellas Europe at the consideration of the report, particularly as no apology was included in the papers for the case. However, the Appeal Board considered that such multiple organisational and cultural failings meant that this was one of the worst cases it had ever had to consider. As stated in the report of the audits there was an institutional failure with respect to compliance. Very senior staff had lied and there was deception on a grand scale. The Appeal Board was appalled and astonished that senior managers from Astellas Europe had made a concerted attempt to deceive it and the PMCPA. In that regard the Appeal Board considered the PMCPA's foresight to interview the Global CEO and President of Astellas Inc during the audit was pivotal in bringing these failings to light. It was a truly shocking state of affairs. The Appeal Board noted that these concerns did not relate to Astellas UK.

This was the third time Astellas Europe had been reported to the Appeal Board by the Panel and the second time Astellas UK had been reported to the Appeal Board by the Panel (including Case AUTH/2747/1/15).

The Appeal Board whilst recognising the difficulties of the situation, considered that Astellas UK should have attempted to exercise greater control on compliance matters in relation to the meeting at issue, the investigation of and response to the complaints and the Panel's reports to the Appeal Board. This was especially important given that Astellas UK was responsible for the acts/omission of its affiliates that fell within the scope of the Code including its UK based European headquarters. Given the information about the lies and deception, it was not surprising that Astellas Europe had asserted itself and taken the lead in responding to Cases AUTH/2747/1/15 and AUTH/2780/7/15.

The Appeal Board noted that Astellas Europe, as a member of EFPIA, was bound by the codes of EFPIA member associations including any applicable sanctions.

The Appeal Board considered that the integrity of self-regulation was reliant upon pharmaceutical companies providing complete and accurate information. The conduct of senior

staff at Astellas Europe had been totally unacceptable and potentially harmful to self-regulation in this regard. It was also disappointing that Astellas UK had not taken firm action. There were multiple failings in these cases. The Appeal Board decided that in accordance with Paragraph 11.3 of the Constitution and Procedure that both Astellas Europe and Astellas UK should again be publicly reprimanded for this failure.

The Appeal Board noted that the UK health professionals who attended the meeting had been provided with two corrective statements and case reports which, given the emergence of new information, gave a misleading account of the arrangements for the meeting at issue. This was wholly unacceptable. Consequently the Appeal Board decided, in accordance with Paragraph 11.3 of the Constitution and Procedure, to require Astellas Europe and Astellas UK to issue a fresh corrective statement to all the UK attendees at the meeting to clarify the position. This would be the third corrective statement. It should refer to both case reports. Under Paragraph 11.3 details, of the proposed content and mode and timing of dissemination of the corrective statement must be provided to the Appeal Board for approval prior to use. [The corrective statement appears at the end of the report.]

The Appeal Board also decided, given the seriousness of the failings, its concerns about the conduct of Astellas as set out above and the responsibility of Astellas UK for its parent company, to report Astellas Europe and Astellas UK to the ABPI Board. This was in accordance with Paragraph 12.1 of the Constitution and Procedure.

### **ABPI BOARD CONSIDERATION OF THE REPORT FROM THE APPEAL BOARD**

The ABPI Board noted that breaches of Clauses 2, 9.1, 12.1, 18.1 and 20.1 of the Code had been ruled. The companies had been reported to the Appeal Board and both had been publicly reprimanded and required to issue corrective statements. The companies had been audited in December 2015 and were to be re-audited in September 2016.

The ABPI Board was extremely concerned at the multiple organisational and cultural failings at Astellas. There was an institutional failure. Very senior staff at Astellas Europe had lied and there was deception on a grand scale which was appalling and shocking.

The totally unacceptable behaviour of senior staff at Astellas Europe was potentially harmful to the integrity of self-regulation which relied upon companies providing complete and accurate information. The ABPI Board noted that Astellas UK was the member of the ABPI and that Astellas UK was responsible for the acts/omissions of affiliates that fell within the scope of the Code including its UK based European headquarters.

The ABPI Board decided that Astellas UK should be suspended from membership of the ABPI for a period of 12 months commencing 24 June. The ABPI Board also decided that it wanted sight of the reports of the September 2016 reaudits of Astellas UK and Astellas Europe so that it could review the position, including the length of the suspension, before the end of 2016. The reaudits must show demonstrable improvements at both companies particularly in relation to corporate culture.

### **APPEAL BOARD FURTHER CONSIDERATION**

Astellas UK and Astellas Europe were re-audited in September 2016 and the report of the audits was considered by the Appeal Board in November.

The Appeal Board noted that although both companies had worked hard to implement the recommendations from the previous audits and to ensure compliance was truly embedded, there was still work to do.

With regard to Astellas Europe, the Appeal Board noted that the institutional failure with respect to compliance was starting to change. Both companies had, *inter alia*, issues with certification. The Appeal Board decided that both should be re-audited in April 2017 and on receipt of the report for those re-audits it would decide whether further sanctions were necessary.

### **ABPI BOARD FURTHER REVIEW**

At its meeting in December 2016, the ABPI Board reviewed the progress made by both companies and the work still to be completed noting that it took time to change culture and to truly embed compliance. It noted the Appeal Board's decision that both companies should be re-audited in April 2017. Although the ABPI Board was encouraged by the improvements and progress made by both Astellas Europe and Astellas UK it decided that the suspension of Astellas UK from membership of the ABPI should continue. The ABPI Board would review the position in June 2017 after the re-audits.

### **APPEAL BOARD FURTHER CONSIDERATION**

Astellas UK and Astellas Europe were re-audited in April 2017 and the report of the audits was considered by the Appeal Board in May 2017.

The Appeal Board noted that Astellas UK and Astellas Europe were now working more closely and there was more open communication with staff. Both companies had been working to implement the recommendations of the previous audits and to ensure compliance was embedded. However, the Appeal Board noted the number of issues highlighted in the report and that there was still much work to be done.

The Appeal Board accepted that it took a long time to change culture but it was not convinced that progress was being made at an appropriate speed particularly given the issues that had come to light in Cases AUTH/2883/10/16, AUTH/2939/2/17 and AUTH/2940/2/17. This was particularly worrying given the level of scrutiny the companies were under. In the view of the Appeal Board, Astellas had much work still to do.

In relation to Case AUTH/2780/7/15 the Appeal Board decided that both companies should be re-audited in October 2017 at the same time as the audits required in Cases AUTH/2939/2/17 and AUTH/2940/2/17 and the re-audit in Case AUTH/2883/10/16 (Astellas UK only).

The Appeal Board noted the outcome of the audit in Case AUTH/2883/10/16 and the re-audits in Case AUTH/2780/7/15, the decisions to report Astellas UK to the ABPI Board in relation to Case AUTH/2883/10/16 and Astellas UK and Astellas Europe in relation to Cases AUTH/2939/2/17 and AUTH/2940/2/17. It also noted its concerns regarding the lamentable lack of concern for patient safety and wholly inadequate oversight and control. Whilst noting this was a matter for the ABPI Board, the Appeal Board's view was that Astellas UK was not ready to resume membership of the ABPI and the suspension should continue.

### **ABPI BOARD FURTHER REVIEW**

At its meeting in June 2017 the ABPI Board agreed with the Appeal Board's comments and concerns about the re-audits in April 2017.

The ABPI Board noted and endorsed the Appeal Board's views about the total failure of the companies' systems in relation to the control of prescribing information, the lamentable lack of concern for patient safety, wholly inadequate oversight and control and initial lack of urgency. It was a woeful state of affairs.

The ABPI Board gave serious consideration to expelling Astellas UK from membership of the ABPI. However, it noted the commitments from Astellas Europe, the global company and of the new UK General Manager. The companies had made voluntary admissions and it was now imperative that the October re-audits showed significant progress.

The ABPI Board decided that it would extend the suspension of Astellas UK from membership of the ABPI for another 12 months. This further period would run uninterruptedly from the initial period of suspension and would then amount to the maximum suspension (two years) allowed under the ABPI Articles of Association.

The ABPI Board also decided that it wanted sight of the report of the October 2017 re-audits of Astellas UK and Astellas Europe so that it could review the position before the end of 2017. If the report of the re-audits did not show significant improvement and progress at both companies, then the ABPI Board would consider expelling Astellas UK from membership of the ABPI. The companies should consider undergoing an external assessment of progress, particularly in relation to risk management of compliance in the broadest sense, ie including matters beyond the scope of the Code, with the outcome to be available at the time of the October 2017 re-audits.

The ABPI Board also decided that the MHRA should be advised of the ABPI Board's very serious concerns about the conduct of Astellas UK and Astellas Europe particularly in relation to the matters concerning patient safety. EFPIA should also be updated and asked to ensure the EFPIA Board was informed of the position.

## **APPEAL BOARD FURTHER CONSIDERATION**

Astellas UK and Astellas Europe were re-audited in October 2017 and the report of the re-audit was considered in November. The Appeal Board noted that as these were the fourth audits of the companies and given that Astellas UK was currently suspended from membership of the ABPI, it expected substantial progress and improvements from both companies. This expectation had not been met. The Appeal Board acknowledged that some progress had been made. The companies must take prompt action to implement the findings and recommendations in the report of the October 2017 re-audits.

The Appeal Board accepted that it took time to change a company's culture. In this regard, the Appeal Board noted that there had been positive changes in the company culture. However, it was not convinced that the expected progress was being made, especially since the April 2017 re-audits.

Overall, the Appeal Board's view was that the rate of progress was inadequate and that the companies were not where they should be. There was still much work to do. The Appeal Board queried whether there was an element of structural inertia or perhaps fear of wrongdoing which was inhibiting or slowing the rate of progress.

Despite its criticisms, the Appeal Board noted the positive steps taken by the leadership of Astellas to engage more broadly with staff and drive changes.

The Appeal Board decided that both companies should be re-audited in April 2018. At which point it expected the 2018 global staff survey to demonstrate improvements at Astellas Europe and Astellas UK.

Whilst noting that this was entirely a matter for the ABPI Board, the Appeal Board's view was that if the report of the October 2017 re-audits and Astellas' response had come at the end of the two year suspension limit, then Astellas would have fallen well short of the standard required to resume membership of the ABPI. Unless substantial progress was seen in the report of the re-audits in April 2018, in the Appeal Board's view, Astellas UK would be at serious risk of a recommendation that it be expelled from membership of the ABPI.

### **ABPI BOARD FURTHER CONSIDERATION**

The ABPI Board noted the Appeal Board's comments and concerns about the re-audits in October 2017 and the additional information provided by Astellas.

With regard to the external assessment of progress, particularly in relation to risk management of compliance in the broadest sense ie including matters beyond the scope of the Code, the ABPI Board noted the information provided by Astellas.

Following a change in tone from the top of Astellas, the ABPI Board recognised that meaningful progress had been made by the companies. The ABPI Board understood the difficulty inherent in making wide-sweeping cultural changes, and how long it took for those changes to become fully embedded within a large organisation. However, the ABPI Board acknowledged Astellas' clear commitment to further improvement.

The ABPI Board noted Astellas' statement that its materials were compliant in May 2017 in relation to issues of patient safety.

The ABPI Board also decided that it wanted sight of the report of the April 2018 re-audits of Astellas UK and Astellas Europe so that it could review the position before the end of the current suspension in June 2018.

The ABPI Board decided that taking all the circumstances into account it would take no further action at this stage in relation to the expulsion of Astellas from membership of the ABPI. The suspension from membership of the ABPI would remain in place until June 2018.

The ABPI Board also decided that the MHRA should be advised of the position. EFPIA should also be updated and asked to ensure that the EFPIA Board was informed of the position.

### **APPEAL BOARD FURTHER CONSIDERATION**

In response to a request from the Appeal Board Astellas provided further information which showed that matters raised by the Appeal Board in November were being addressed more promptly than previously indicated.

## **APPEAL BOARD FURTHER CONSIDERATION**

Astellas UK and Astellas Europe were re-audited in April 2018 and the report of the re-audits was considered in May 2018.

The Appeal Board noted the detailed responses from Astellas to the report of the April 2018 re-audits including that it was an accurate reflection of the work undertaken.

The Appeal Board noted the results of the 2018 staff survey and the progress made. Numerical increases had been shown in a number of parameters since the previous survey in July 2017. There were concerns about the comments made by staff. The Appeal Board also noted the differences in the Astellas UK results which were generally better than the Astellas Europe results. The Appeal Board considered that the Astellas Europe management committee scores although improved were still not where they should be.

The Appeal Board noted the comments in the report of the April 2018 re-audits and considered that both the leadership of Astellas Europe and Astellas UK had engaged with staff to bring about progress. There was still work to be done. The Appeal Board noted one of the recommendations was that members of the leadership team at Astellas Europe should be held to account and be challenged on compliance matters.

The Appeal Board accepted that it took time to change a company's culture. In this regard, the Appeal Board noted that there had been further positive changes in the company culture and this needed to be continued. The Appeal Board noted that there had been some positive compliance initiatives. The discussion fora and communications continued and progress had been made including ensuring staff had time to complete training.

The Appeal Board noted that whilst as a percentage there had been a significant increase in the number of job bags, the overall number was still low. As Astellas increased its activities it must remain extremely vigilant to compliance requirements in particular in relation to certain higher risk activities such as patient support programmes, product launches etc. The true test of the compliance framework in Astellas and its approach would be when activity levels including higher risk activities were increased and the company was operating at business as usual.

The Appeal Board considered that, at long last, the re-audits in April 2018 showed that progress had been made and that the companies were building on momentum started in summer 2017. The Appeal Board was concerned that these were the fifth audits of each company and that the first audits were in December 2015. It was extraordinary that it had taken so long to demonstrate meaningful change. The overall impression from the report of the April 2018 re-audits was that Astellas was showing improvement and momentum. However, whilst the companies had reached a certain level, given all the circumstances including that Astellas UK had been suspended from membership of the ABPI and that the Appeal Board still had concerns, the Appeal Board decided that Astellas Europe and Astellas UK should each be re-audited at the end of the first quarter of 2019 to ensure that the improvements and the momentum continued and were built upon.

On the information before it, and noting that Astellas UK was still to respond to the PMCPA in relation to matters raised following completion of the consideration of a complaint concerning Astellas UK, Case AUTH/2984/10/17, the Appeal Board decided that sufficient progress had been made by the companies such that the Appeal Board did not consider that it warranted a



recommendation for the expulsion of Astellas UK from membership of the ABPI when the matter came before the ABPI Board on 5 June 2018.

### **ABPI BOARD FUTURE CONSIDERATION**

In June 2018 the ABPI Board noted the comments from both the Appeal Board and Astellas.

The ABPI Board noted the limited information provided about matters raised in Case AUTH/2984/10/17. This was still to be considered by the PMCPA and the Appeal Board and was not before the ABPI Board for consideration.

The view of the Appeal Board was clear. The ABPI Board agreed with the Appeal Board's views and assessment of the re-audits and concluded that meaningful progress had now been made.

The ABPI Board believed that the culture in the companies had improved and noted that much of this had been led by the General Manager of Astellas UK. However, the Board recognised the importance of an ongoing commitment to ensure sustained culture change. On reviewing all the material, the ABPI Board had concerns about the sustainability of the changes made given that there had already been five audits/re-audits, and especially as further types of activity were still to be fully re-introduced across the companies.

The ABPI Board therefore decided that it wanted to see the report of the 2019 re-audits and be informed of major developments including the outcome of Case AUTH/2984/10/17.

In the circumstances, there was no need for the ABPI Board to consider expelling Astellas UK from membership of the ABPI. The suspension would end on 24 June 2018 and Astellas would revert to full membership of the ABPI.

Astellas should be cognisant of this ongoing sustainability requirement and monitoring (particularly in light of the matters still to be concluded in Case AUTH/2984/10/17) when communicating about the Board's decision.

The ABPI Board also decided that the MHRA should be advised of the position and that EFPIA should be updated and asked to ensure that the EFPIA Board was informed of the position.

### **APPEAL BOARD FURTHER CONSIDERATION**

Astellas UK and Astellas Europe were re-audited in April 2019 and the report of the re-audits was considered in May 2019.

The Appeal Board noted the detailed response from Astellas Europe and Astellas UK to the report of the April 2019 re-audits.

The Appeal Board noted two new senior appointments; a new President EMEA Operations who joined Astellas in July 2018 and a new General Manager, Astellas UK who was appointed from April 2019.

The Appeal Board noted from the report of the April 2019 re-audits that it appeared that a more compliant culture was embedded within Astellas with improved communication. It was essential that this was maintained.

The Appeal Board considered that Astellas UK must ensure a proper professional approach to investigating and responding to any complaint under the Code such that the shortcomings in Case AUTH/2984/10/17 were not repeated. The Appeal Board noted that an audit had not been required in Case AUTH/2984/10/17. The case had, in accordance with established practice, been discussed as part of an examination of the company's culture at the re-audits.

The Appeal Board noted that these were the sixth audits/re-audits of each company and that the first audits were in December 2015. The Appeal Board considered that, on the information provided in the report of the April 2019 re-audits, it appeared that the companies had made further improvements, that this would be maintained and broadly the companies were where they should be. The Appeal Board, however, remained very concerned about the amount of time it had taken Astellas to reach this point. The Appeal Board noted that Astellas stated that it would follow up on the issues identified in the report of the April 2019 re-audits and it was committed to maintaining its approach to embedding a sustainable compliance culture. The Appeal Board noted a number of activities/actions were due to be undertaken. On the understanding that this work was completed, that the progress shown to date was continued and a company-wide commitment to compliance was maintained, the Appeal Board decided that, on the basis of the information in the report of April 2019 re-audits, no further action was required in relation to Case AUTH/2780/7/15, Case AUTH/2883/10/16, Cases AUTH/2939/2/17 and AUTH/2940/2/17.

The Appeal Board noted that the audit/re-audits in these four cases had been required by the Appeal Board. They had not been required by the ABPI Board. Nonetheless, the Appeal Board noted the ABPI Board's request to see the report of the April 2019 re-audits.

At the re-audits in April 2019 it was noted that the MHRA decided that Astellas advertising materials should be submitted for review. This was introduced for all new materials issued since 1 December 2018.

## **ABPI BOARD UPDATE**

In June 2019 the ABPI Board received an update as requested. It noted the comments from both the Appeal Board and Astellas and the improvements made.

<b>Complaint received</b>	<b>8 July 2015</b>
<b>Undertaking received</b>	<b>5 November 2015</b>
<b>Appeal Board consideration</b>	<b>15 October 2015, 21 January 2016, 25 February, 28 April, 11 November, 25 May 2017, 16 November, 7 December, 17 May 2018, 22 May 2019</b>
<b>ABPI Board consideration</b>	<b>7 June 2016, 6 December 2016, 6 June 2017, 5 December, 5 June 2018</b>

<b>ABPI Board update</b>	<b>4 June 2019</b>
<b>First corrective statement was required in Case AUTH/2747/1/15 and issued on 1 July 2015</b>	
<b>Second corrective statement issued</b>	<b>4 January 2016</b>
<b>Panel reconvened</b>	<b>6 April 2016</b>
<b>Third corrective statement issued</b>	<b>28 June 2016</b>
<b>Interim case report first published</b>	<b>15 December 2015</b>
<b>Case completed</b>	<b>22 May 2019</b>

\* \* \* \* \*

Astellas Pharma Europe and Astellas UK sent copies of the case report and the company's corrective statement to all UK attendees at the meeting. The materials were sent on 4 January 2016.

Astellas Pharma Europe Ltd was required to provide UK delegates who attended its meeting on 27/28 February 2014 with a corrective statement. The meeting (Case AUTH/2747/1/15) was ruled in breach of the ABPI Code of Practice for the Pharmaceutical Industry and the corrective statement was sent on 1 July 2015.

Following a second complaint (Case AUTH/2780/7/15), the Code of Practice Panel ruled that Astellas Pharma Europe and Astellas UK had provided the Panel and the Appeal Board with false and incomplete information regarding the selection criteria for attendees at the meeting. High standards had not been maintained and this had brought discredit upon, and reduced confidence in, the pharmaceutical industry. As a result Astellas Pharma Europe and Astellas UK have been required to issue this further corrective statement and to circulate a copy of the published report for Case AUTH/2780/7/15 which contains full details and is enclosed.

Details of these cases (Case AUTH/2747/1/15 and Case AUTH/2780/7/15) are also available on the PMCPA website ([www.pmcpa.org.uk](http://www.pmcpa.org.uk)).

\* \* \* \* \*

Astellas Europe and Astellas UK sent copies of the case report and the company's corrective statement to all UK attendees at the meeting. The materials were sent in on 28 June 2016.

#### 'Corrective Statement

Astellas Pharma Europe and Astellas UK have already sent corrective statements with regard to the meeting you attended in Milan on 27/28 February 2014.

Following a complaint under the ABPI Code of Practice for the Pharmaceutical Industry (Case AUTH/2747/1/15) breaches of the Code were ruled and the Code of Practice

Panel reported Astellas Pharma Europe to the Code of Practice Appeal Board which required the company to issue a corrective statement. This was sent to you on 1 July 2015.

A subsequent complaint (Case AUTH/2780/7/15) revealed that the information provided in Case AUTH/2747/1/15 about the selection criteria for attendees at the meeting had been false and incomplete. The Panel reported Astellas Pharma Europe and Astellas UK to the Appeal Board which required a further corrective statement to be issued. This was sent to you on 4 January 2016.

Following the provision of further information from Astellas Pharma Europe which showed the extent to which the Panel and the Appeal Board had been misled and the seniority of the personnel involved, the Panel again reported Astellas Pharma Europe and Astellas UK to the Appeal Board. As a result Astellas Pharma Europe and Astellas UK have been required as part of a number of sanctions to issue another corrective statement and to circulate a copy of the updated report for Case AUTH/2780/7/15 which contains full details.

Details of these cases (Case AUTH/2747/1/15 and Case AUTH/2780/7/15) which include details of the subsequent suspension of Astellas UK from membership of the ABPI are also available on the PMCPA website ([www.pmcpa.org.uk](http://www.pmcpa.org.uk)).