CASE AUTH/3514/5/21

EX-EMPLOYEE v ASTRAZENECA

AstraZeneca advisory board

An ex-employee raised concerns about what he/she described as a scientific debrief meeting run by AstraZeneca UK after the American Society of Haematology (ASH) congress in December 2020.

The complainant alleged that the only reason AstraZeneca chose to run this activity was to promote its product pre-licence and raise awareness of the timelines to EMA (European Medicines Agency) approval.

The complainant alleged that the goal was to gather company-directed insights on off-licence data without relevant contracts in place and without following company advisory board standard operating procedures (SOPs) or the PMCPA guidance. When these concerns were raised internally, it was allegedly stated 'that a degree of risk needs to be taken here and the PMCPA are unlikely to find out as none of the HCPs [health professionals] will complain'.

The complainant alleged that the data which was presented was carefully selected by the AstraZeneca medical team and was therefore not a true hands-off approach with AstraZeneca also selecting which data should be shown to the wider group of health professionals; there was no evidence of a true 2-way exchange.

The detailed response from AstraZeneca is given below.

The Panel noted that a Steering Committee meeting was held prior to a 3 hour virtual advisory board meeting, following the ASH Congress. The Panel noted AstraZeneca's submission that the objectives of the advisory board in question were to understand the implications of the latest Chronic Lymphocytic Leukaemia (CLL) clinical trial data being presented at the congress and how that data might impact clinical practice for patients with CLL in the UK.

The Panel noted AstraZeneca's submission that in preparation for the advisory board it had triaged several hundreds of abstracts down to 22 based on a balanced selection of topics relevant to the practice of medicine in CLL. The Steering Committee was provided with the abstract short list and selected 14 of these for the Advisory Board, three of which were related to AstraZeneca's product acalabrutinib.

The Panel noted AstraZeneca's submission that as part of contracted preparatory work ahead of the Advisory Board, all expert advisors were allocated 2-3 abstracts each by the Steering Committee to facilitate discussions at the meeting. Each advisor was asked to spend no more than three minutes presenting data and the total presentation time was approximately 42 minutes for the 14 abstracts and the meeting totalled 180 minutes. The

Panel queried whether some of the presentations would be delivered in the allotted time noting the number of data comprehensive slides to be presented.

The Panel noted that the meeting in question was inconsistently described throughout the documentation as a scientific exchange meeting and/or an advisory board. The Panel noted that the Code referred to the legitimate exchange of medical and scientific information during the development of a medicine, the requirements for which were, in the Panel's view, very different to an advisory board. AstraZeneca acknowledged that any reference to the term 'scientific exchange' was an oversight that should have been identified and could potentially have been misunderstood by some individuals. The Panel noted it was important that companies were clear about their definition of 'scientific exchange' to avoid confusion internally and externally and to help ensure associated activities were compliant with the Code. In this regard, the Panel noted that it appeared that the complainant might have been confused by use of the term scientific exchange.

The Panel noted AstraZeneca's submission that contrary to the complainant's allegation, acalabrutinib (Calquence) received its marketing authorisation prior to the Steering Committee, ASH 2020 and the advisory board at issue. The Panel therefore considered that Calquence had not been promoted prior to the grant of its marketing authorisation and ruled no breach of the Code.

Whilst the Panel had some concerns with regard to the arrangements and documentation for the advisory board in question, it did not consider that the complainant had established, on the balance of probabilities, that the advisory board meeting was in fact promotional, and thus it ruled no breaches of the Code in relation to the requirement for prescribing information and certification. Whilst the Panel had some concerns regarding the inconsistent descriptions of the meeting in question, the Panel noted that the complainant had not established that the meeting was promotional and therefore it could not be disguised in this regard; the Panel ruled no breach of the Code.

The Panel noted AstraZeneca's submission that the advisory board consisted of seven consultant haematology advisors chosen from a pool of more than 700 active consultant haematologists in the UK based on their expertise in CLL, the UK CLL treatment landscape, and their ability to provide AstraZeneca with expert insights and advice on the potential impact of the key ASH Congress data and represented a mixture of district general and teaching hospitals. The Panel considered that there was no evidence that AstraZeneca had failed to satisfy the requirements of the Code in relation to the selection of health professionals and the number retained and ruled no breach of the Code.

In relation to the allegation that not all health professionals were contracted with a fee for service contract, the Panel noted that AstraZeneca had provided copies of signed contracts for the seven named advisors. Whilst the Panel had some concerns about the contract overall, the Panel considered that on balance it was sufficiently clear that the contract was for participation in an advisory board. The Panel noted that the contract for one steering committee advisor was signed three days after the Steering Committee and therefore ruled a breach of the Code in that regard.

In relation to the allegation that there was no legitimate reason for the activity, the Panel noted AstraZeneca's submission that the objectives of the advisory board in question were to understand the implications of the latest CLL clinical trial data being presented at

the congress and how that data might impact clinical practice for patients with CLL in the UK. Overall, the Panel considered that the complainant had not established that a legitimate need for the services had not been clearly identified in advance of requesting the services and entering into arrangements and no breach of the Code was ruled on this point.

The Panel noted that AstraZeneca had been asked to respond to Clause 18.1 which referred, *inter alia*, to the prohibition on the provision of gifts, pecuniary advantages and benefits in connection with the promotion of medicines or as an inducement to prescribe, supply, administer recommend or buy and sell any medicine. The Panel noted that the complainant had referred to payment of registration fees but did not consider that the complainant had directly or indirectly raised an allegation in relation to inducements. The Panel further noted its comment above that the meeting was not promotional. In addition, the Panel noted AstraZeneca's submission that six of the advisors were already attending the ASH Congress and their registration/attendance was not funded by AstraZeneca. Only one of the advisors had their registration paid for by AstraZeneca in advance of the ASH Congress and the funding for this individual was in no way linked to any other commitment or obligation to attend AstraZeneca meetings after the ASH Congress, including the Advisory Board in question. The Panel therefore ruled no breaches of the Code.

The Panel noted that the complainant had not provided any details to support his/her allegations that there was any disparagement of other company's medicines, or health professions, nor that any breach of undertaking had occurred. It was not for the Panel to make out a complainant's allegation. The Panel thus ruled no breaches of the Code.

The complainant alleged that the presenters had not passed the ABPI exam which, in the Panel's view, was not applicable to the meeting in question; the Panel ruled no breach of the Code.

The Panel noted AstraZeneca's submission that its internal investigation ascertained that no member of its current staff recollects that a senior leader stated. '…a degree of risk needs to be taken here and the PMCPA are unlikely to find out as none of the HCPs will complain' or similar. The Panel considered that the complainant had not established that concerns raised internally were dismissed or that the statement in question was made as alleged and no breach of the Code was ruled in that regard.

The Panel noted that the complainant had not identified how the SOP or PMCPA guidance had not been followed. It was not for the Panel to infer the reason for the allegation. The Panel noted AstraZeneca's submission that the arrangements were in line with its internal SOPs. In the absence of further information from the complainant, the Panel ruled no breach of the Code.

Whilst noting its comments above that the meeting in question appeared to be non-promotional, the Panel nonetheless had concerns about the arrangements. In the Panel's view, a meeting which amounted to the legitimate exchange of medical and scientific information during the development of a medicine was very different to an advisory board under the Code. It was important to be clear about the nature of the meeting, particularly when participants were paid. In such circumstances the company had to be mindful about the impression created by the arrangements. The Panel noted the frequency and prominence and potentially misleading references to scientific

exchange on key documents. The Panel noted that the invitation prominently on the front page referred to the meeting in question solely as a virtual scientific exchange meeting. The first paragraph of the invitation on page 2 asked invitees to participate in a non-promotional virtual scientific exchange meeting. The second paragraph on that page stated that the meeting objectives were to gain the invitees' insights on the impact of clinical evidence presented at ASH on the treatment landscape of CLL within the UK. Details of their expected role in relation to presenting abstracts was set out. The abstract list for the Steering Committee referred to the meeting in question twice and unqualified as a scientific exchange meeting. The slides for the Steering Committee referred to the meeting in question as a 'scientific advisory meeting' and as a scientific exchange meeting. The arrangements were approved internally using the Advisory Board Needs Assessment form which described the meeting title as scientific exchange. The Panel also noted the references to a scientific exchange meeting in the advisors' contracts as outlined above and similar references on the slides used at the advisory board meeting. The Panel noted that AstraZeneca acknowledged that such references had the potential to mislead. In addition, the Panel considered that any potentially misleading impression was compounded by the references in the Advisory Board slides to the advisory board as a 'partnership between UK clinicians and AstraZeneca' and as an 'HCP-led project' both of which were inconsistent with arrangements for an advisory board. It was unclear to the Panel why these concerns had not been picked up during the approval process. High standards had not been maintained and a breach of the Code was ruled.

The Panel noted its concerns outlined above. However, noting the Panel's view that the advisory board in question was non promotional and that certain documents referred both to the attendees' advisory and participatory role and the questions that AstraZeneca wished to address, the Panel, on balance, did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and no breach was ruled.

An ex-employee raised concerns about what he/she described as a scientific debrief meeting held on 16 December 2020 which was run by AstraZeneca UK Limited after the American Society of Haematology (ASH) congress.

COMPLAINT

The complainant stated that his/her concern with this debrief meeting was that it was run post-congress under the guise of a scientific exchange, however, AstraZeneca chose all of the data to be discussed and presented at this debrief meeting so it was not a truly hands-off approach. The complainant alleged that the promotional meeting was run by the medical team which, in essence, should have been non-promotional in nature. It appeared that this was actually, in fact, an advisory board which was held to gather insights and to also present off-licence data to health professionals.

The complainant stated that a true scientific debrief meeting would have been steered by the health professionals discussing any data that they deemed relevant from the congress. The complainant alleged that there seemed to have been a very flagrant and obvious blasé bending of the rules by AstraZeneca by choosing to promote off-licence data and run an 'advisory board' as such where this was probably not the best method to do so and there was no legitimate reason for such an activity. The complainant alleged that the only reason AstraZeneca chose to

run this activity was to promote its product pre-licence and raise awareness of the timelines to EMA (European Medicines Agency) approval.

The complainant alleged there was no relevance to the health professionals selected and it was merely a 'select as many people as possible approach'. Furthermore, not all of the health professionals were contracted with a fee-for-service contract. It was clear in this debrief meeting that the goal was to gather company-directed insights on off-licence data (without relevant contracts in place) and without actually following company advisory board standard operating procedures (SOPs) or the PMCPA guidance. When these concerns were raised internally, they were dismissed and it was stated 'that a degree of risk needs to be taken here and the PMCPA are unlikely to find out as none of the HCPs [health professionals] will complain'.

The complainant found this an extremely dim-witted approach to compliance from a giant such as AstraZeneca, and the senior team within the oncology unit needed to understand that compliance also applied to them. The complainant requested that the PMCPA looked into this particular matter to ensure that it was not repeated.

The complainant explained that the 'scientific exchange/debrief' meeting was normally chaired by 3/4 health professionals who had been delegated by AstraZeneca to attend meetings (under a fee for service contract and with delegate conference fees paid). There was then normally an 'exchange' meeting post congress whereby the 3/4 health professionals that had been selected by AstraZeneca presented the data to a wider group of health professionals who were not under a fee for service contract and should have been selected as being key players in the haematology field or health professionals that treated lymphoma patients and thus had a requirement to know the latest scientific data.

The complainant stated that the data which was presented by the AstraZeneca sponsored health professionals was carefully selected by the AstraZeneca medical team. It was, therefore, not a true hands-off approach with AstraZeneca also selecting which data should be shown to the wider group of health professionals. There was no evidence of a true 2-way exchange by doing so. For this to be a true scientific exchange, the complainant stated that AstraZeneca should have had no influence on the data which was presented by the health professionals chairing the meeting. The complainant provided the highlights deck which was sent post-meeting to attendees. This included some of the products such as acalabrutinib which was discussed (off-licence in this setting).

The complainant requested that the following clauses were addressed: Clauses 2, 3.1, 4.1, 8.1, 8.2, 9.1, 12.1, 12.2, 14.1 (as the deck was promotional and not certified), 16.1 (as the presenters had not passed the ABPI exam), 23.1 and 29.

When writing to AstraZeneca, the Authority asked it to consider the requirements of Clause 18.1 in addition to the clauses cited by the complainant.

RESPONSE

AstraZeneca submitted that the Advisory Board at issue took place on 16 December 2020, following the American Society of Haematology 2020 congress (the 'ASH Congress'). The complainant's allegations were broken down by AstraZeneca as follows:

1 The Advisory Board constituted disguised promotion and was run under the 'guise of scientific exchange' to 'promote their product pre-licence and raise awareness of the EMA approval timelines'.
2 There was a 'flagrant and obviously blasé bending of the rules by AstraZeneca' by 'choosing to run the meeting as an advisory board to promote off-label data'.
3 The goal of the Advisory Board was to 'gather company directed insights on off-licence data without relevant contracts in place'.
4 Health professionals were not appropriately selected for the Advisory Board with a 'select as many people as possible' approach.
5 Neither the relevant company Advisory Board SOP, nor the PMCPA guidance, were being followed.
6 That presenters were not appropriately qualified to chair the Advisory Board having 'not passed the ABPI exam'.
7 Compliance concerns were raised by the complainant and dismissed by the AstraZeneca Oncology Medical Affairs Lead.

AstraZeneca refuted all of these allegations and any suggestion that Clauses 2, 3.1, 4.1, 8.1, 8.2, 9.1, 12.1, 12.2, 14.1, 16.1, 18.1, 23.1 and 29 of the ABPI Code had been breached and asserted that all of the activities conducted in relation to this Advisory Board were executed according to AstraZeneca's SOPs and were entirely permissible within the Code.

AstraZeneca submitted that, in its response to these allegations, it would establish that this was a legitimate, well-planned and well-executed Advisory Board. The subject matter for the Advisory Board was decided independently by an external scientific panel, comprised of two leading UK clinical experts in the field of Chronic Lymphocytic Leukaemia (CLL). The objectives of the meeting were to provide AstraZeneca with strategic insight into the clinical considerations for the medical practice of CLL in the future, whilst also supporting the Haematology Team's medical planning for 2021.

AstraZeneca stated up-front that it neither promoted nor disguised the promotion of any product in any way at the Advisory Board. AstraZeneca also took the complainant's allegations that a Senior Leader in the Oncology Business Unit dismissed concerns with regard to the planning and conduct of this meeting very seriously. Following a thorough investigation, AstraZeneca had ascertained that no member of AstraZeneca's current staff recollected that a senior leader stated *'… a degree of risk needs to be taken here and the PMCPA are unlikely to find out as none of the HCPs will complain*' or anything else to that end. This allegation therefore remained unsubstantiated. AstraZeneca wanted to reassure the PMCPA that if a comment like this had been substantiated by the investigation, then appropriate action would have been taken against the individual, as this was not aligned to the company values nor the company's attitude towards the Code.

During the investigation it was noted that, prior to the meeting taking place, a general discussion was had by the Haematology Team regarding appropriate formats and processes for various meetings. It had been agreed many months earlier that the format for this specific meeting (16 December 2020) would be that of an Advisory Board – it was made clear to the team that an Advisory Board was the most appropriate format, given its intended objectives (ie gaining clinical insight that would inform future medical strategy). The decision to conduct the meeting as an Advisory Board was fully supported by the Senior Oncology Medical Leadership team and the AstraZeneca Advisory Board SOP was followed throughout. AstraZeneca fully encouraged a 'speak-up' culture and welcomed constructive debate from all team members, at all times, however, the decision had been appropriately taken by medical leadership to pursue the

Advisory Board route and the meeting was conducted in line with both SOP guidance and the Code of Practice.

AstraZeneca provided further information on:

- the business needs assessment for the Advisory Board, including the planning process and engagement with the external Steering Committee in the lead up to it;
- the agenda for the Advisory Board and its execution according to plan;
- the selection and engagement of advisors and
- the importance of the insights gained for strategy planning purposes.

Finally, AstraZeneca addressed each of the complainant's allegations according to the relevant clause of the Code in turn.

Background to the post-ASH 2020 Advisory Board Meeting, December 2020

Acalabrutinib (Calquence) received a license from the EMA for first line (1L) Chronic Lymphocytic Leukaemia (CLL) and relapsed/refractory (RR) CLL on 5 November 2020 following an assessment process that started in October 2019. The Summary of Product Characteristics (SPC) for acalabrutinib was provided.

The ASH Congress was held annually and was widely known amongst the clinical and scientific community as 'THE key haematology congress', worldwide. As a result, the importance of this meeting and the potential to address business needs through obtaining insights from external experts on the latest clinical innovations after the congress, was a key tactic outlined in the Haematology Team's medical plans from early 2020 (January). The ASH Congress took place between 5-8 December 2020; AstraZeneca therefore planned a virtual Advisory Board meeting via Zoom to take place one week later, on 16 December 2020.

The objectives of this Advisory Board were to understand the implications of the latest CLL clinical trial data being presented at the congress and how they might impact clinical practice for patients with CLL in the UK. The Advisory Board provided an important forum for UK clinical experts in CLL to provide their opinion on the key data disclosed and their impact on clinical practice. These insights would then form the basis for aspects of the Haematology franchise's medical strategy for 2021, particularly with regard to the educational needs of UK health professionals.

Abstract selection prior to the Advisory Board

As part of the initial abstract selection process, the AstraZeneca Haematology Medical Team triaged several hundreds of abstracts down to a total of 22 abstracts, based on a balanced selection of topics relevant to the practice of medicine in CLL, such as patient sub-groups, fixed versus continuous treatment paradigms, innovative study designs, new trends in MRD-guided treatments, novel synergistic combinations for longer remissions, treatment sequencing studies and BTKi differentiation. As part of the preparation for an Advisory Board, it was entirely permissible for a company to have input into broad types of content for discussion.

A Steering Committee comprising of two clinical expert advisors and UK thought leaders in the field of CLL met on 27 November 2020 to consider these 22 abstracts for discussion at the Advisory Board, with a view to selecting approximately 15 for discussion (total number being

guided by the amount of discussion time available with the experts). The Steering Committee selected 14 abstracts from those 22, three of which were related to AstraZeneca's acalabrutinib. This final selection was based on scientific merit and pertinence to the advancement of clinical practice in CLL alone. To be clear, AstraZeneca played no role, nor exerted any influence on the selection of these final 14 abstracts.

The set-up of the Advisory Board

The Advisory Board consisted of seven consultant haematology advisors with specialist expertise in CLL. These individuals were chosen from a pool of more than 700 active consultant haematologists in the UK and represented a mixture of district general hospitals and teaching hospitals. All advisors were selected and contracted based on their expertise in CLL, the UK CLL treatment landscape and their ability to provide AstraZeneca with expert insights and advice on the potential impact of the key ASH Congress data. AstraZeneca's Advisory Board SOP was followed and appropriate contracts were agreed with these individuals. For completeness, AstraZeneca provided all relevant documentation. With these facts in mind, the complainant's allegation that '*AstraZeneca selected as many people as possible*' was plainly incorrect.

To address a further query raised by PMCPA, six of the advisors were already attending the ASH Congress and their registration/attendance was NOT funded by AstraZeneca. Only one of the advisors had their registration paid for by AstraZeneca in advance of the ASH Congress. The funding for this individual was in no way linked to any other commitment or obligation to attend AstraZeneca meetings after the ASH Congress, including this Advisory Board.

Selection of Chairpersons

Due to the nature of the Advisory Board, it was AstraZeneca's opinion that two chairs were needed to facilitate the discussions effectively. A Consultant Haematologist who was one of the Steering Committee members was contracted to be the expert 'Chairperson' for this meeting. This individual was specifically chosen for this role due to his/her extensive expertise and thought leadership in the CLL space. The second Chairperson was an AstraZeneca staff member from the medical department was fully conversant with the Code as well as AstraZeneca's SOPs and was well-qualified to serve as a co-chair for this meeting.

In addition there was a second member of AstraZeneca staff present in the Advisory Board who was responsible for the logistics of the meeting. AstraZeneca also employed one agency staff member, who was tasked with taking minutes. All AstraZeneca representatives were required to attend as they were all performing different duties to facilitate the Advisory Board – co-chair, meeting logistics and medical writing. AstraZeneca was satisfied that the ratio of advisors and AstraZeneca representatives was appropriate.

Advisor preparatory work

As part of contracted preparatory work ahead of the Advisory Board, all expert advisors were allocated 2-3 abstracts each by the Steering Committee to facilitate discussions at the meeting. Each advisor was asked to spend no more than three minutes presenting data from their assigned abstract to allow ample time for discussion. The total presentation time was approximately 42 minutes for the 14 abstracts and the meeting totalled 180 minutes. This represented a 77%:23% split in terms of time allocation for presentation versus discussion [sic]. This was in line with AstraZeneca's Advisory Board SOP guidance and it remained satisfied that

this balance was appropriate. AstraZeneca reiterated that the abstracts were presented by the experts themselves, not AstraZeneca members of staff.

The Advisory Board

At the outset of the Advisory Board, the AstraZeneca chair highlighted to all attendees the non-promotional nature of the meeting and reiterated AstraZeneca's strict adherence to the Code. The objectives of the Advisory Board were clearly articulated to the advisors at the beginning of the meeting, explaining the role of the Steering Committee members and how insights derived from the discussions would influence AstraZeneca's medical plans in 2021. Finally, the advisors were told that those discussions would centre around four key focus areas of clinical practice, (i) the impact of these new data on near-term CLL practice in the UK, (ii) the impact on treatment sequencing regarding new and existing medicines, (iii) treatment strategies in specific CLL patient subgroups with high unmet medical need and (iv) other novel emerging trends in CLL treatment.

Outputs following the Advisory Board

An example output from the Advisory Board was the 'Lymphoma Highlights from ASH 2020' reactive medical information deck that was also submitted by the complainant in this case. This was a non-promotional, reactive, post-congress scientific highlights report which contained insights gathered during the meeting. This non-promotional post-congress report was developed by the AstraZeneca Haematology Medical Team without any commercial input or involvement. The report was subsequently made available strictly as a non-promotional medical information resource, to be used for reactive requests from UK health professionals practicing in CLL.

This Advisory Board also provided important learnings for the AstraZeneca Haematology Medical Team as it helped inform and shape medical plans for 2021 and beyond to shape the long-term strategy, particularly with regard to factors that contributed to prescriber choice between venetoclax-based (fixed-duration) and BTKi (continuous)-based therapies. Importantly, AstraZeneca also learned their concerns around the cardiovascular tolerability of acalabrutinib, and treatment sequencing dilemmas following novel treatment combinations of anti-CD20, BCL inhibitor and BTK inhibitor-based therapies. In addition, emerging clinical studies around the use of Minimum Residual Disease 'MRD' as a treatment endpoint in the future management of CLL was also discussed at the meeting.

Scientific Exchange Meeting terminology

Upon thorough review of all of the documentation associated with this Advisory Board, although it was fully compliant with AstraZeneca's SOP, it became apparent that the words 'Scientific Exchange Meeting' were present in the Advisory Board meeting title in several documents. In retrospect, AstraZeneca acknowledged that any reference to the term 'scientific exchange' was an oversight that should have been identified, and so could potentially have been misunderstood by some individuals.

AstraZeneca emphasised that the words 'scientific exchange' in the title had no bearing on the case and must not be taken as evidence of an intention to run this meeting as anything other than an Advisory board. Again, it had been decided and made clear to the Haematology team several months beforehand that this meeting would be run as an Advisory Board, the documentation was clear that the meeting would be an Advisory Board, and it was well-

executed as an Advisory Board, in full accordance with the Advisory Board SOP and the UK Code. Moreover, all of the advisors were contracted to provide advisory board services accordingly – they were clear on the expectations for the meeting, both in the run up to it and on the day regarding their roles and responsibilities as contracted experts, and they raised no concerns before, during or after the event.

AstraZeneca also pointed out that there was no such thing as a 'Scientific Exchange Meeting' – indeed, it was unclear as to why this language was used at all. This investigation had highlighted to AstraZeneca Senior Leadership that, out of an abundance of caution, AstraZeneca believed it would be valuable to conduct some internal training for its Oncology team on the need for accurate and consistent language when describing the format of meetings in order to avoid any potential confusion internally or externally in the future. AstraZeneca would commit to rolling this training out as a matter of urgency.

Response to alleged breaches of the Code

AstraZeneca strongly refuted all of these allegations. As such, the PMCPA would note that no element of the meeting or any of the supporting meeting materials could be deemed as being 'promotional'. Furthermore, great care was taken to follow the relevant advisory board SOP to ensure that the non-promotional nature of this Advisory Board remained intact .

Clause 2 of the Code (Discredit to, and reduction of, confidence in the Industry)

AstraZeneca took its responsibilities under the Code very seriously. AstraZeneca was confident this matter had not brought discredit to, or reduced confidence in, the pharmaceutical industry and so did not constitute a breach of Clause 2. There was no evidence that this Advisory Board was a 'disguised promotional meeting,' AstraZeneca had established above that this was a well-planned and executed Advisory Board. In reviewing the advisor's feedback post-Advisory Board, AstraZeneca could confirm that it was positive – all advisors voted that they would not change anything to improve the meeting. AstraZeneca did not receive any complaints from the advisors in attendance about the process and way the Advisory Board was conducted. In summary, AstraZeneca strongly denied any allegation of a breach of Clause 2.

Clause 3.1 of the Code (Marketing Authorisation)

AstraZeneca categorically refuted any allegations made by the complainant that the Advisory Board was planned to promote its product pre-licence or to raise awareness of the timelines for EMA approval. As set out in the background section above, this was a non-promotional Advisory Board where the objectives of the meeting were clear. Contrary to the complainant's allegations, acalabrutinib had already obtained its EMA licence for 1L and RR CLL on 5 November 2020, a date preceding both the steering committee and the Advisory Board. AstraZeneca also had no influence on the final 14 abstracts that were selected for discussion – this was solely at the discretion of the Steering Committee. AstraZeneca strongly refuted the complainant's accusations that AstraZeneca was promoting its product pre-licence and denied any breach of Clause 3.1.

Clause 4.1 of the Code (Prescribing Information and other Obligatory Information)

AstraZeneca denied any breach of this clause, given the non-promotional nature of this Advisory Board. As the requirement for displaying the prescribing information (PI) was for promotional materials only, AstraZeneca had not included the PI in any of the materials for the

Advisory Board. The Code did not require that PI was included within Advisory Board materials (a non-promotional meeting). AstraZeneca had fully complied with the requirements of this clause and refuted any allegations of breaching Clause 4.1.

Clauses 8.1 and 8.2 of the Code (Disparaging references)

AstraZeneca refuted allegations made by the complainant that this clause had been breached. At no point were other medicines, products or pharmaceutical companies disparaged during this Advisory Board. In addition, AstraZeneca took great care to ensure that its relationships with health professionals were appropriate and professional and it denied any disparagement of any health professional. Feedback obtained from the advisors who responded (6 out 7 advisors responded) was entirely positive. Thus, AstraZeneca strongly refuted any allegations of a breach under Clause 8.1 or 8.2.

Clause 9.1 of the Code (High Standards)

AstraZeneca believed that high standards were maintained at all times and refuted any allegations of breaching this clause. AstraZeneca had provided a detailed outline of its rationale, planning and execution of this Advisory Board. AstraZeneca strongly refuted any allegations of breaching this clause.

Clauses 12.1 and 12.2 of the Code (Disguised promotion)

Clause 12.1

This was an unfounded allegation which AstraZeneca strongly refuted. As could be noted from AstraZeneca's detailed background section above, the non-promotional nature of this Advisory Board was evident throughout the planning and execution phases. At no point did AstraZeneca promote its product at this Advisory Board as it was wholly non-promotional in nature. The Advisory Board was planned in line with strict adherence to the Code and internal SOPs.

Clause 12.2

As stated above, this was a non-promotional Advisory Board with no relevance to this clause. There were no activities such as market research, clinical assessments, post-marketing surveillance or experience programmes that would fall under the scope of this clause. Thus, AstraZeneca refuted allegations of breaching Clause 12.2.

Clause 14.1 of the Code (Certification and examination)

The complainant alleged a breach of Clause 14.1, namely the requirements for certification of promotional materials. Given the non-promotional nature of the Advisory Board, there were no requirements for certification of associated materials. All materials relating to the Advisory Board were approved in accordance with AstraZeneca's SOPs and were examined by two AstraZeneca nominated medical signatories to ensure that it did not contravene the Code or any other relevant statutory requirements. AstraZeneca refuted the allegation of breaching Clause 14.1.

Clause 16.1 of the Code (Training)

The complainant alleged a breach of Clause 16.1 and stated that '*the presenters had not passed the ABPI exam*'. AstraZeneca strongly refuted any suggestion that its internal co-chair was not adequately trained or conversant with the Code. In addition, given the clear non-promotional nature of this Advisory Board, and the non-promotional nature of the AstraZeneca chair's role at the company, there was no additional requirement for an ABPI examination to be undertaken, as incorrectly suggested by the complainant. AstraZeneca refuted allegations of having breached Clause 16.1.

Clause 18.1 of the Code (Prohibition on inducements and inappropriate payments)

The PMCPA had asked AstraZeneca to bear in mind the requirements of this clause. As outlined above, AstraZeneca had presented a clear rationale in its selection, contracting and payment processes for the advisors with no inappropriate inducements or payments being made to any of its Advisory Board attendees. Thus, AstraZeneca had fully complied with the requirements of Clause 18.1 of the Code.

Clause 23.1 of the Code (The use of consultants)

The complainant alleged that health professionals were not appropriately selected for the meeting because of an alleged intention to 'select as many people as possible' and a lack of contracts being in place for the advisors. AstraZeneca denied this allegation entirely and had found no evidence to support this claim. From the outset, careful consideration was given to the advisors selected to attend the Advisory Board, all being consultant haematologists with expertise in CLL, who could provide AstraZeneca with expert insights and advice required. AstraZeneca had demonstrated that the number of advisors for the Advisory Board was reasonable to achieve its identified need. Each advisor was contracted in accordance with the rules set out in AstraZeneca's Fair Market Value document and in line with its Advisory Board SOP.

Clause 29 of the Code (Compliance with undertakings)

The complainant had alleged a breach of Clause 29 but had not provided any further details on this. AstraZeneca noted that the PMCPA had also written to the complainant asking for further information which it had not received. In the absence of any specifics, AstraZeneca refuted any allegations that there was a breach of Clause 29. AstraZeneca was committed to maintaining high standards in all of its activities and in complying with the ABPI Code of Practice. AstraZeneca provided strong evidence to refute allegations of breaching this clause.

Summary of AstraZeneca's position

In summary, AstraZeneca had established that the Advisory Board in question was conducted compliantly and within the ABPI Code of Practice and in line with its internal SOPs. The insights obtained from this Advisory Board helped guide the Haematology Medical Team's strategy for 2021 and beyond. The use of the words 'scientific exchange' in the meeting title had no bearing on the case – the decision to conduct the meeting as Advisory Board had been made clear many months beforehand and the team executed the planning and the meeting itself to the highest standards. As a result of the internal investigation into this case, a training need had been identified in order to avoid any potential misunderstanding of terminology either internally or externally in the future. Finally, AstraZeneca reiterated that it neither promoted nor disguised the promotion of any product in any way at the Advisory Board – this was clearly evidenced by the manner in which the meeting had been planned (ie the Steering Committee selected the

subject matter for the meeting with no influence from AstraZeneca) and all of the supporting materials provided.

In conclusion, AstraZeneca strongly refuted any suggestions that the Code had been breached. AstraZeneca had robust processes in place to ensure that it operated consistently to the highest of standards, and it was satisfied that, in this case, those processes had been followed.

In response to a request for further information from the Panel, AstraZeneca stated that there was no separate written briefing provided to AstraZeneca staff who AstraZeneca explained were inviting health professionals to attend the meeting as this was not required by its Advisory Board SOP. AstraZeneca explained that all staff were expected to engage and invite external experts in accordance with its SOP, a copy of which had been previously provided. AstraZeneca provided a copy of the invitation to the meeting in question.

PANEL RULING

The Panel noted that it was acceptable for companies to pay health professionals and others for relevant advice. It was important that when a company interacted with health professionals as consultants rather than prescribers that the arrangements withstood independent scrutiny given that such arrangements invariably involved the payment of funds. The arrangements for consultancy meetings such as advisory board meetings had to comply with the Code, particularly Clause 23 of the 2019 Code. To be considered a legitimate advisory board the selection and number of participants should stand up to independent scrutiny; each should be chosen according to their expertise such that they would be able to contribute meaningfully to the purpose and expected outcomes of the advisory board. The number of participants should be limited so as to allow active participation by all. The company must have a legitimate unanswered business question which the meeting should address. The agenda should allow adequate time for discussion. The number of meetings and the number of participants should be limited and driven by need and not the invitees' willingness to attend. The nature of the meeting should be made clear to invitees and participants: invitations to participate should clearly state the purpose of the advisory board meeting, the expected advisory role and the amount of work to be undertaken. If an honorarium was offered, it should be made clear that it was a payment for such work and advice. Honoraria must be reasonable and reflect the fair market value of the time and effort involved.

The Panel noted that a Steering Committee meeting was held in November 2020 and AstraZeneca held a 3 hour virtual advisory board meeting on 16 December 2020, following the American Society of Haematology (ASH) Congress meeting held on 5-8 December 2020. The Panel noted AstraZeneca's submission that the objectives of the advisory board in question were to understand the implications of the latest CLL clinical trial data being presented at the congress and how that data might impact clinical practice for patients with CLL in the UK.

The Panel noted the complainant's allegation that what he/she described as the debrief meeting after the congress was held under the guise of scientific exchange. The complainant described the meeting in question as promotional as it was not hands off, all the data had been chosen by AstraZeneca. The complainant considered the meeting to be an advisory board and that there was no legitimate reason for it. The complainant alleged that the only reason AstraZeneca chose to run this activity was to promote its product pre-licence and raise awareness of the timelines to EMA (European Medicines Agency) approval.

The Panel noted AstraZeneca's submission that in preparation for the advisory board it had triaged several hundreds of abstracts down to 22 based on a balanced selection of topics relevant to the practice of medicine in CLL. The Steering Committee was provided with the abstract short list which stated, *inter alia*, 'Any ASH CLL abstract can be included in the final shortlist of 12-15. The intention of this initial list is to make the task of the steering committee manageable, but no abstract will be included or excluded without the agreement of steering committee members. All CLL abstracts will be made available to steering committee members at the steering committee meeting'. The Panel noted AstraZeneca's submission that the Steering Committee, which comprised two clinical expert advisors and UK thought leaders in the field of CLL, selected 14 of these abstracts for discussion by the Advisory Board, three of which were related to AstraZeneca's product acalabrutinib. The Panel noted AstraZeneca's submission that this final selection was based on scientific merit and pertinence to the advancement of clinical practice in CLL alone; AstraZeneca played no role, nor exerted any influence on the selection of the final 14 abstracts.

The Panel noted that, in principle, the role and arrangements for the Steering Committee were not necessarily unacceptable in relation to its preparatory work for the advisory board so long as the abstract selection was made clearly within the context of addressing a genuine business question for AstraZeneca and was supported by the documentation. In this regard, the Panel further noted that slide 6 of the Steering Committee meeting slides under the heading 'ASH 2020: our rationale', stated, *inter alia*,: that the 'ASH 2020 Scientific Exchange Meeting is a partnership between UK clinicians and AZ' and 'Your insights will help inform the materials that will be produced to educate UK clinicians in the weeks following ASH'. Slide 7 headed 'ASH 2020 scientific exchange meeting objectives' described the meeting at issue as an 'HCP-led project' and referred to the meeting aims as 'Review key data from ASH pertinent to the evolution of treatment for CLL' and 'Gain insights on the impact this data may have for the treatment of CLL in the UK'.

The Panel noted that slide 6 of the Steering Committee slides referred to above was also included in the slides shown at the advisory board in question titled AstraZeneca UK: American Society of Haematology (ASH) 2020 Virtual Scientific Exchange Meeting.

The Panel noted AstraZeneca's submission that as part of contracted preparatory work ahead of the Advisory Board, all expert advisors were allocated 2-3 abstracts each by the Steering Committee to facilitate discussions at the meeting. Each advisor was asked to spend no more than three minutes presenting data from their assigned abstract to allow ample time for discussion. The total presentation time was approximately 42 minutes for the 14 abstracts and the meeting totalled 180 minutes. The Panel queried whether some of the presentations would be delivered in the allotted time noting the number of data comprehensive slides to be presented.

AstraZeneca submitted that at the outset of the Advisory Board in question, a co-chair highlighted the non-promotional nature of the meeting and that the objectives of the Advisory Board were also clearly articulated to the advisors at the beginning of the meeting, explaining the role of the Steering Committee members and how insights derived from the discussions would influence AstraZeneca's medical plans in 2021. The Panel further noted AstraZeneca's submission that the advisors were told that those discussions would centre around four key focus areas of clinical practice (i) the impact of these new data on near-term CLL practice in the UK, (ii) the impact on treatment sequencing regarding new and existing medicines, (iii) treatment strategies in specific CLL patient subgroups with high unmet medical need and (iv) other novel emerging trends in CLL treatment. Slide 7 of the advisory board slides headed ASH

2020 scientific exchange meeting objectives referred to reviewing 'key data from ASH 2020 pertinent to the evolution of treatment for CLL' and 'gain insights on the impact this data may have for the treatment of CLL in the UK'.

The Panel noted that the meeting in question was inconsistently described throughout the documentation as a scientific exchange meeting and/or an advisory board. The Panel noted that the supplementary information to Clause 3 of the 2019 Code referred to the legitimate exchange of medical and scientific information during the development of a medicine, the requirements for which were, in the Panel's view, very different to an advisory board which had to satisfy the requirements outlined above. The Panel noted that both meetings the legitimate exchange of medical and scientific information during the development of a medicine and advisory board meetings were non promotional activities under the Code. AstraZeneca acknowledged that any reference to the term 'scientific exchange' was an oversight that should have been identified and could potentially have been misunderstood by some individuals. The Panel noted that in its experience companies occasionally used the phrase 'scientific exchange'. It was important that companies were clear about their definition of this phrase to avoid confusion internally and externally and to help ensure associated activities were compliant with the Code. In this regard, the Panel noted that it appeared that the complainant might have been confused by use of the term scientific exchange.

Whilst noting the Panel had some concerns about the arrangements, it was nonetheless obliged to consider the matter in relation to the allegations raised by the complainant.

The Panel noted AstraZeneca's submission that contrary to the complainant's allegation, acalabrutinib (Calquence) received its marketing authorisation from the EMA for first line (1L) Chronic Lymphocytic Leukaemia (CLL) and relapsed/refractory (RR) CLL on 5 November 2020 which was prior to the Steering Committee, ASH 2020 and the advisory board at issue which were held on 27 November, 5-8 December and 16 December 2020, respectively. The Panel therefore considered that Calquence had not been promoted prior to the grant of its marketing authorisation and ruled no breach of Clause 3.1.

Whilst the Panel had some concerns with regard to the arrangements and documentation for the advisory board in question, as noted above, it did not consider that the complainant had established, on the balance of probabilities, that the advisory board meeting on the 16 December 2020 was in fact promotional, and thus it ruled no breach of Clause 4.1, in relation to the requirement for prescribing information to be provided in all promotional material, and no breach of Clause 14.1, in relation to the alleged failure to certify relevant material. The Panel noted AstraZeneca's submission that all materials relating to the advisory board were approved in accordance with AstraZeneca's SOPs and were examined by two AstraZeneca nominated medical signatories. Whilst the Panel had some concerns regarding the inconsistent descriptions of the meeting in question, the Panel noted that the complainant had not established that the meeting was promotional and therefore it could not be disguised in this regard; the Panel ruled no breach of Clause 12.1.

The Panel did not consider that the complainant had raised an allegation in relation to Clause 12.2 which related to market research, clinical assessments, post-marketing surveillance and experience programmes, post-authorization studies and the like and thus it ruled no breach of that Clause.

The Panel noted the complainant's allegation that there was no relevance to the health professionals selected and it was merely a 'select as many people as possible approach'. The

Panel noted AstraZeneca's submission that the advisory board consisted of seven consultant haematology advisors chosen from a pool of more than 700 active consultant haematologists in the UK based on their expertise in CLL, the UK CLL treatment landscape, and their ability to provide AstraZeneca with expert insights and advice on the potential impact of the key ASH Congress data and represented a mixture of district general and teaching hospitals. The Panel considered that the complainant had not provided any evidence to support his/her allegation on this point and the Panel, noting AstraZeneca's response, considered that there was no evidence that AstraZeneca had failed to satisfy the requirements of Clause 23.1 in relation to the selection of health professionals and the number retained. The Panel ruled no breach of Clause 23.1 on this point.

In relation to the allegation that not all health professionals were contracted with a fee for service contract, the Panel noted that AstraZeneca had provided copies of signed contracts for the seven named advisors. The Panel noted that Clause 23.1 required a written contract to be agreed in advance which specified the nature of the services to be provided and the basis for payment of those services. Whilst the title of the event was described in the contract as the AZ UK American Society of Haematology (ASH) 2020 Virtual Scientific Exchange Meeting, the services to be provided section described the meeting as a virtual scientific exchange but referred to the health professional as an advisor and referred to their participation. A header described the agreement as an advisory board fee for service contract and section 1 of the agreement referred to the health professional acting as an advisor or chair and providing their professional input and expertise in the relevant therapy area. Section 1 also described the meeting as an advisory board to allow AstraZeneca to gather important information from the advisors. Whilst the Panel had some concerns about the contract overall, the Panel considered that on balance it was sufficiently clear that the contract was for participation in an advisory board. The Panel considered that the Steering Committee was an integral part of the arrangements and the contracts for the two steering committee advisors covered their role at both the Steering Committee and the advisory board. In this regard the Panel noted that the contract for one steering committee advisor, was signed three days after the Steering Committee, on 30 November. The Panel therefore ruled a breach of Clause 23.1 in that regard.

In relation to the allegation that there was no legitimate reason for the activity, the Panel noted that Clause 23.1 required a legitimate need for the service to be clearly identified in advance of requesting services and entering into arrangements. The Panel noted AstraZeneca's submission that the objectives of the advisory board in question were to understand the implications of the latest CLL clinical trial data being presented at the congress and how that data might impact clinical practice for patients with CLL in the UK. The Panel noted that the Advisory Board Needs Assessment form described the overall objective of the meeting as to gain feedback, guidance and insights from UK HCPs involved in the management of CLL and to: review key data from ASH 2020 pertinent to the evolution of treatment for CLL and to gain insights on the impact this data may have for treatment of CLL in the UK. The discrete business objectives section gave further details about the advice sought. The form stated that AstraZeneca did not have the answer to the question already and there had not been any previous advisory boards regarding ASH2020 data for UK only HCPS. The planned output was an internal post meeting report. Overall, the Panel considered that the complainant had not established that a legitimate need for the services had not been clearly identified in advance of requesting the services and entering into arrangements. No breach of Clause 23.1 was ruled on this point.

The Panel noted that AstraZeneca had been asked to respond to Clause 18.1 which referred, *inter alia*, to the prohibition on the provision of gifts, pecuniary advantages and benefits in

connection with the promotion of medicines or as an inducement to prescribe, supply, administer recommend or buy and sell any medicine. The Panel noted that the complainant had referred to payment of registration fees but did not consider that the complainant had directly or indirectly raised an allegation in relation to inducements. The Panel further noted its comment above that the meeting was not promotional. In addition, the Panel noted AstraZeneca's submission that six of the advisors were already attending the ASH Congress and their registration/attendance was not funded by AstraZeneca. Only one of the advisors had their registration paid for by AstraZeneca in advance of the ASH Congress and the funding for this individual was in no way linked to any other commitment or obligation to attend AstraZeneca meetings after the ASH Congress, including the Advisory Board in question. The Panel therefore ruled no breach of Clause 18.1 and the similar requirement in Clause 23.1.

The Panel noted that the complainant, who had the burden of proving his/her complaint on the balance of probabilities, had cited Clauses 8.1, 8.2 and 29. The complainant had not provided any details to support his/her allegations that there was any disparagement of other company's medicines, or health professions, nor that any breach of undertaking had occurred. It was not for the Panel to make out a complainant's allegation. The Panel thus ruled no breach of Clauses 8.1, 8.2 and 29 of the 2019 Code.

The complainant alleged that the presenters had not passed the ABPI exam and cited Clause 16.1 in this regard. The Panel noted that Clause 16.3 of the 2019 Code covered the requirement for representatives to take an appropriate examination and Clause 1.7 defined a representative as someone calling on members of the health professions and other relevant decision makers in relation to the promotion of medicines which, in the Panel's view, was not applicable to the meeting in question advisory board attendees in the circumstances of this case. Clause 16.1 required that all relevant personnel including representatives and members of staff, and others retained by way of contract, concerned in any way with the preparation or approval of material or activities covered by the Code must be fully conversant with the Code and the relevant laws and regulations. Noting the above and based on the complainant's allegation, the Panel ruled no breach of Clause 16.1.

In relation to the allegation that concerns raised internally were dismissed, the Panel noted that the complainant had the burden of proving his/her complaint on the balance of probabilities. The Panel noted AstraZeneca's submission that its internal investigation ascertained that no member of its current staff recollects that a senior leader stated. '…a degree of risk needs to be taken here and the PMCPA are unlikely to find out as none of the HCPs will complain' or similar. The Panel considered that the complainant had not established that concerns raised internally were dismissed or that the statement in question was made as alleged and no breach of Clause 9.1 was ruled in that regard.

In relation to the allegation that the advisory board meeting in question had been run without following the requisite Advisory Board SOP or PMCPA guidance, the Panel noted that the complainant had not identified how the SOP or PMCPA guidance had not been followed. It was not for the Panel to infer the reason for the allegation. The Advisory Board Meetings SOP was a detailed 12 page document. The Panel noted AstraZeneca's submission that the arrangements were in line with its internal SOPs. In the absence of further information from the complainant, the Panel ruled no breach of Clause 9.1 of the Code.

Whilst noting its comments above that the meeting in question appeared to be non-promotional, the Panel nonetheless had concerns about the arrangements. In the Panel's view, a meeting which amounted to the legitimate exchange of medical and scientific information during the

development of a medicine was very different to an advisory board under the Code. It was important to be clear about the nature of the meeting, particularly when participants were paid. In such circumstances the company had to be mindful about the impression created by the arrangements. The Panel noted the frequency and prominence and potentially misleading references to scientific exchange on key documents. The Panel noted that the invitation prominently on the front page referred to the meeting in question solely as a virtual scientific exchange meeting. The first paragraph of the invitation on page 2 asked invitees to participate in a non-promotional virtual scientific exchange meeting. The second paragraph on that page stated that the meeting objectives were to gain the invitees' insights on the impact of clinical evidence presented at ASH on the treatment landscape of CLL within the UK. Details of their expected role in relation to presenting abstracts was set out. The abstract list for the Steering Committee referred to the meeting in question twice and unqualified as a scientific exchange meeting. The slides for the Steering Committee referred to the meeting in question as a 'scientific advisory meeting' (slide 5) and as a scientific exchange meeting at slides 6, 7, 9 and 15. The arrangements were approved internally using the Advisory Board Needs Assessment form which described the meeting title as scientific exchange. The Panel also noted the references to a scientific exchange meeting in the advisors' contracts as outlined above and similar references on the slides used at the advisory board meeting. The Panel noted that AstraZeneca acknowledged that such references had the potential to mislead. In addition, the Panel considered that any potentially misleading impression was compounded by the references in the Advisory Board slides to the advisory board as a 'partnership between UK clinicians and AstraZeneca' (slide 6) and as an 'HCP-led project' (slide 7) both of which were inconsistent with arrangements for an advisory board. It was unclear to the Panel why these concerns had not been picked up during the approval process. High standards had not been maintained and a breach of Clause 9.1 was ruled.

The Panel noted its concerns outlined above in relation to Clause 9.1 of the Code. However, noting the Panel's view that the advisory board in question was non promotional and that certain documents referred both to the attendees' advisory and participatory role and the questions that AstraZeneca wished to address, the Panel, on balance, did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and no breach was ruled.

Complaint received **24 May 2021**

Case completed **9 August 2022**