CASE AUTH/3825/9/23 *NO BREACH OF THE CODE*

BEIGENE v JANSSEN

Complaint about a presentation at a Janssen symposium during the European Haematology Association (EHA) conference in June 2023

CASE SUMMARY

This case concerned Janssen UK's responsibilities under the Code in relation to a UK speaker's presentation at a Janssen Europe symposium during a conference in Frankfurt, Germany. Janssen UK had supported a delegation of UK health professionals (including the speaker) to attend the conference.

There was an appeal by Janssen UK of one of the Panel's rulings.

The outcome under the 2021 Code was:

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 3.4	**Requirement to comply with all applicable codes, laws and regulations**
No Breach of Clause 3.6	**Requirement that materials and activities must not be disguised promotion**
No Breach of Clause 5.1	**Requirement to maintain high standards at all times**
No Breach of Clause 6.1	**Requirement that claims/information/comparisons must not be misleading**
No Breach of Clause 8.2 (Panel's breach ruling overturned at appeal)	**Requirement that events/meetings involving travel outside the UK, unless the company's only involvement is to support a speaker to present at the meeting, must be certified**
No Breach of Clause 10.1	**Requirement that companies must not provide inappropriate hospitality**

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

FULL CASE REPORT

A complaint was received from BeiGene about Janssen.

COMPLAINT

The complaint wording is reproduced below with typographical errors corrected:

> "On behalf of Beigene UK Ltd I wish to make a complaint about a symposium arranged by Janssen during the EHA meeting in June this year. We have engaged in inter-company dialogue which raised our concern that the meeting was not certified in advance by the UK affiliate. We have been unable to resolve this matter, hence this formal complaint.
>
> On 8 June Janssen Pharmaceutica NV ('Janssen') hosted an industry symposium at the EHA 2023 Congress in Frankfurt with the title: 'YOU HAVE A NEW MATCH! PAIRING TREATMENTS AND PATIENTS TOGETHER FOR OPTIMAL TREATMENT IN CHRONIC LYMPHOCYTIC LEUKAEMIA (CLL)'. One of the speakers, [named doctor], presented the current treatment options and clinical data in the R/R CLL setting in a presentation titled 'TAILORING TREATMENT IN CLL: SELECTING THE RIGHT TREATMENT AND DURATION FOR THE RIGHT PATIENT IN THE RELAPSE SETTING'. The presentation excluded the ALPINE trial and therefore did not comply with Janssen's obligation to provide accurate, balanced, and complete information about medicinal products in a presentation to healthcare professionals. The ALPINE clinical trial evaluated zanubrutinib against ibrutinib in the R/R CLL setting and is the only clinical trial in which one BTK-i (zanubrutinib) demonstrated superiority over another BTK-i (ibrutinib). During inter-company dialogue this was attributed to a technical fault with the presentation slides.
>
> **Alleged breaches:**
>
> **Clause 2.** Activities or materials must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry.
>
> **Clause 3.4** Companies must comply with all applicable codes, laws and regulations to which they are subject**.**
>
> **Clause 3.6** Materials and activities must not be disguised promotion.
>
> **Clause 5.1** High standards must be maintained at all times.
>
> **Clause 6.1** Information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. They must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis.
>
> Material must be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine.
>
> It is our position that it was reasonable to expect a UK audience to have attended the symposium and therefore it fell within scope of the ABPI Code. Janssen UK facilitated travel arrangements for the UK speaker and supported a delegation of UK HCPs to attend EHA. Polling during the meeting confirmed that UK HCPs were indeed in the audience.

During inter-company dialogue it appeared that Janssen UK believed the meeting arrangements and materials did not require certification as they did not invite or direct UK HCPs to attend.

Alleged Breaches:

Clause 8.2 (14.2) Presentations by UK Speakers at Events/ Meetings Held Outside the UK

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

Clause 10.1 (22.1) Events/Meetings Organised by Affiliates Outside the UK

Companies should remind their affiliates outside the UK that the ABPI Code must be complied with if UK health professionals attend events/meetings which they organise, regardless of whether such events/meetings occur in the UK or abroad.

Clause 10.1 (22.1) Certification and Examination of Events/Meetings

Pharmaceutical companies must ensure that all events/meetings which are planned are examined to see that they comply with the Code. Companies must have a written document that sets out their policies on events/meetings and hospitality and the associated allowable expenditure. In addition, events/meetings which involve travel outside the UK must be certified as set out in Clause 8.2

We believe that Janssen have breached several clauses of the ABPI Code as the UK affiliate is responsible for the activities of their overseas affiliates where those activities come in scope of the Code."

JANSSEN'S RESPONSE

The response from Janssen is reproduced below:

"Thank you for your letter of 22nd September 2023 regarding the above complaint from BeiGene UK under the Code of Practice for the Pharmaceutical Industry. The complaint relates to a symposium sponsored by Janssen's European organisation - Janssen Pharmaceuticals ('**JPNV')** at the European Haematology Association (EHA) conference hosted in Frankfurt on 8th June 2023.

BeiGene initiated intercompany dialogue, stating that the presentation by a Janssen funded UK speaker the [named doctor] did not comply with Janssen's obligation to provide accurate, balanced, objective, sufficiently complete and non-misleading information about

medicinal products in a presentation to healthcare professionals based on omission of data from Beigene's ALPINE study.

BeiGene Europe initially raised this concern to JNPV in a letter dated the 14th of June 2023[copy provided]. JPNV responded to BeiGene Europe on the 22nd of June 2023 [copy provided], explaining that whilst the slide referring to the ALPINE trial was in the submitted showreel[copy provided], it was not shown during the live presentation due to a technical issue when the speaker switched from the polling system back to the slide show system. JPNV explained that the speaker did not immediately notice that [they] had skipped the slide, however [they] did talk about the ALPINE trial and relevant data when asked about it during the panel discussion. In addition, Janssen made provision to include on the EHA on-demand platform the slide referring to the ALPINE trial, along with commentary explaining why it was not shown in the live event, together with direction as to where in the recording the speaker discussed the data[copy provided].

Despite receiving a comprehensive response explaining that a technical error had occurred during the [named doctors]'s presentation, BeiGene Europe did not acknowledge JPNV's response, choosing instead to repeat the allegations via its UK affiliate in a letter to Janssen UK dated the 30th of June, initiating intercompany dialogue.

Over the course of the intercompany dialogue, in both the initial and subsequent responses, Janssen UK made clear to BeiGene UK that its European organisation had raised the same concerns under applicable European and host country regulations to JPNV who organised the meeting. As Janssen UK had no role whatsoever in relation to the symposium or presentation BeiGene UK were encouraged to continue dialogue with the most relevant Janssen team, JPNV.

To be transparent, Janssen UK also confirmed to Beigene UK that it had facilitated the arrangements for a small delegation of UK HCPs to attend the EHA congress with no direction or invitation to attend any Janssen-sponsored symposium whilst there. In keeping with its obligations under the ABPI Code, Janssen UK certified all travel arrangements for UK supported delegates which included travel arrangements for the [named doctor] who was part of the UK delegation[copy provided].

Alleged breaches

BeiGene UK have alleged several breaches of the Code without being specific as to the basis for each of those allegations. As example, it is unclear as to why Beigene believes Janssen has attempted to disguise promotion (Clauses 3.6 and 15.6).

As outlined earlier Janssen UK had no role whatsoever in the organisation of the symposium. Janssen Europe responded fully to Beigene Europe stating Janssen's position that the content presented at the symposium was balanced and relevant to the objectives of the symposium.

The technical issue could not have been predicted. Beyond Janssen Europe already having addressed the accidental omission during the live symposium AND implementing corrective actions on the EHA on-demand platform, Beigene UK failed to clarify what additional action/outcome they were seeking during intercompany dialogue. Instead, their

focus shifted to whether the speaker slides should have been certified, alleging several other breaches of the Code.

In addition to our response above the PMCPA has requested additional information and supporting documents as summarised below.

1. *Details of involvement of Janssen UK in the arrangements for the meeting*
   Janssen UKs involvement in the arrangements for the meeting is as described previously.
2. *Support for speaker(s)/delegates prior to and during the event*
   A copy of the letter of support (redacted) to the [named doctor] outlining Janssen's level of support as a delegate to the EHA conference[copy provided]. This is the same as that issued to each of the 9 other UK supported HCP delegates.

3. *Details of Janssen UK personnel present at EHA and at the symposium*
   [List of Janssen UK personnel and job titles provided]
   Janssen UK employees who attended the symposium (**in bold**) did so for their own educational purposes; they did not have any active role.

4. *Any invitations for the symposium sent to delegates*
   UK delegates were not invited to the symposium by Janssen UK. Please see logistics letter [copy provided] that was sent to each delegate supported by Janssen UK. As can be seen there was no reference or invitation to any Janssen sponsored symposium.

   All delegates to the conference regardless of country of origin were made aware of the various industry-sponsored symposia through materials circulated directly by the EHA conference organisers. Please see Janssen symposia advert for EHA conference mobile App [copy provided] and as appeared on the inside front cover of the Conference abstract book[copy provided].

5. *Clarification of Janssen UK oversight of the presentations/speaker slides*
   Janssen UK had no role in briefing the speaker or in reviewing any of the speaker slides.

6. *Copies of certificates approving any presentations and arrangements for individuals supported by Janssen UK*
   a. Speaker slides were not reviewed or certified by Janssen UK
   b. We have included an extract of Janssens HealthCare Compliance (HCC) system for AQP approval of delegate arrangements[copy provided]
   c. Also included an extract from our HCC system confirming that the Fee for Service for the [named doctor] was managed by Janssen's European team[copy provided]

7. *Arrangements for individuals supported by Janssen UK e.g. delegates (please state the qualifications of your signatories)*
   a. Arrangements for individuals supported by Janssen UK[copies provided]
   b. Janssen signatory list in November 2022, showing qualifications of signatories[copy provided].

It is Janssen's view that Beigene's concern in relation to the symposium was appropriately addressed and we refute Beigene's allegations of any breaches of the Code."

PANEL RULING

The Panel noted that the requirements of Clause 5.3 of the Constitution and Procedure of the Code (relating to intercompany dialogue) had been complied with by the complainant, Beigene. Beigene had attempted intercompany dialogue with the company complained about (Janssen UK) but that process had been unsuccessful.

The Panel interpreted this complaint as being about two matters:

1. Did the UK ABPI Code apply to the complaint, given it related to a symposium that took place in Frankfurt, Germany?

2. If the Code *did* apply, had the symposium led to a breach of the Code by Janssen UK?

Was the complaint within the scope of the Code?

The first question that the Panel considered was whether the symposium complained about was within the scope of the Code. The symposium was held in Frankfurt, Germany on 8 June 2023 as part of the 2023 European Haematology Association ("EHA") conference. It was the third of three symposia organised and supported by Janssen's European organisation; Janssen Pharmaceutica NV ("JPNV").

The symposium was entitled "*You have a new match! Pairing treatment and patients together for optimal treatment in CLL*" and lasted 90 minutes. It featured a panel of four health professionals; one each from the USA, Ireland, Dubai and the UK. The health professional from the UK was a UK doctor who was part of the Panel discussion at the end of the symposium, but also gave a 20 minute presentation on chronic lymphocytic leukaemia ("CLL") entitled "*Tailoring treatment in CLL: selecting the right treatment and duration for the right patient in the relapse setting*".

Although Janssen UK's position was that they had "*no role whatsoever in the organisation of the symposium*", the Panel disagreed. The Panel concluded that it was clear from the materials provided to it that there was a sufficient UK nexus to bring this matter within the scope of the Code. This was based on the following reasons:

1. The presenter of this session was a UK doctor based at a UK hospital ("the Presenter").

2. The letter of invitation to the conference, that was sent to the Presenter began "*On behalf of Janssen-Cilag Limited*…" i.e. the invitation letter was sent from Janssen UK; not JPNV.

3. The delegate support pack for the conference was also sent to the Presenter by an employee of Janssen UK and on behalf of Janssen UK.

4. An additional nine UK health professionals were invited to attend the

conference. Janssen UK confirmed in its response to the PMCPA that the same delegation support correspondence was sent to these nine UK health professionals as was sent to the Presenter. The Panel interpreted that to mean that it was also sent from Janssen UK.

5. The Panel noted that it would be reasonable to assume that at least some of these nine UK health professionals would likely attend a symposium organised by JPNV given that they had been invited to the conference by JPNV's UK affiliate.

6. The Panel accepted the submission by Beigene that there was a poll during the presentation that confirmed UK health professionals were in the audience.

7. The Panel also considered it reasonable to assume that the EHA's annual conference would have additional UK-based audience members beyond just those invited by Janssen UK.

The Panel concluded that, based on all of the above reasons, it is clear that there is a sufficient connection to the UK, and the ABPI Code therefore applied to the complaint.

The Chronic Lymphocytic Leukaemia symposium and the ALPINE clinical trial slide

The second part of this complaint was that during the Presenter's 20 minute presentation at the CLL symposium, a slide on the different treatment options for CLL was not shown to the live audience.

Given this was a slide that referred to the ALPINE clinical trial, Beigene considered this to be a critical slide ("the ALPINE slide") because it showed that zanubrutinib (a Beigene product) demonstrated superiority over ibrutinib (a Janssen product).

Beigene alleged that this matter was a breach of clauses 2, 3.4, 3.6, 5.1, 6.1, 8.2 and 10.1 of the Code.

Paragraph 2.2 of the Constitution and Procedure states that the complainant has the burden of proving their complaint on the balance of probabilities. All complaints are judged on the evidence provided by the parties.

Clause 6.1

Janssen UK's response to the PMCPA was that the omission of the ALPINE slide was a technical error that happened due to the Presenter clicking between a poll and then back to the slideshow. Janssen UK accepted that the ALPINE slide was not shown during the live presentation. However, the Panel accepted that Janssen took steps to mitigate the effect of this omission:

1. The Presenter referred to the ALPINE trial and relevant data later on in the symposium, during a panel discussion.

2. The full slide deck was available to symposium attendees after the event via the EHA on-demand platform. That included the ALPINE slide, together with an explanation for

why it was omitted in the live presentation and a direction on where in the recording the Presenter's discussion of the ALPINE trial could be found.

The Panel considered the requirements of Clause 6.1 that information must be "*accurate, balanced, fair, objective and unambiguous*". The Panel also noted in particular the second paragraph of Clause 6.1 that "*Material must be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine*".

Although the ALPINE slide was just one of 20 very detailed and content-heavy slides, the Panel did consider that slide to be a critical one, given that it showed that zanubrutinib (a rival Beigene product) demonstrated superiority over ibrutinib (a Janssen product). In that sense, it was an important part of providing balance and objectivity in relation to the options available for CLL.

However, the Panel considered that this was most likely a technical error on the part of the Presenter and a simple mistake in clicking through slides. Although this was a Janssen symposium and it was responsible for the slides and the content, the Panel did acknowledge that the Presenter was not a Janssen employee.

It was also clear from the slideshow that the ALPINE slide did follow-on from a slide in which there was a QR code inviting the audience to participate in a poll. Following the Presenter's error in returning from the poll back to the correct proceeding slide, the Panel concluded that the potential for the audience to be misled had been mitigated by reference to the ALPINE trial and relevant data during the Panel discussion. Although the Panel was unable to access the recording of the symposium, screenshots were provided showing that the EHA on-demand platform included the full slides along with commentary about why it was not shown during the symposium and a description of how to view the ALPINE trial discussion during the Panel session. Beigene (which has the burden of proving its complaint) had not provided any evidence to show that Janssen had not done this.

The Panel based its ruling partly on this being a technical error by the Presenter, and partly that the error appeared to the Panel to have been comprehensively corrected by the Presenter (during the live Panel discussion) and afterwards by Janssen (in the materials and explanation given on the EHA on-demand platform).

Overall, the Panel did not believe that those attending the symposium, nor those viewing the recording and the materials afterwards, would have been misled or unaware of the ALPINE trial and data.

Given those factors, and the totality of the evidence provided by Beigene and Janssen, on balance the Panel did not consider that Beigene had established that the live presentation or the recorded version subsequently available were misleading. The Panel therefore **ruled no breach of Clause 6.1**.

Clause 3.6

It was not clear to the Panel why Beigene considered the presentation to be disguised promotion. Noting that the PMCPA was not an investigatory body and that complainants bore the burden of establishing their case on the balance of probabilities, the Panel **ruled no breach of Clause 3.6**.

Clause 8.2

The Panel looked at the Supplementary Information ("SI") to Clause 8.2 which provided that:

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

The Panel has taken account of the following factors:

1. The Panel's conclusion above that there were UK delegates at the symposium.

2. Janssen UK confirmed in its response to the PMCPA that it facilitated the attendance of UK health professionals at the conference (including the Presenter) and therefore it knew in advance that there would be UK delegates attending.

3. Janssen UK confirmed in its response to the PMCPA that it did not certify the Presenter's slides.

4. The SI to Clause 8.2 states essentially that it is only where there are no UK delegates and no UK company involvement, that slides do not need to be certified.

The Panel acknowledged that the symposium at which the Presenter delivered the slides was organised by JPNV. However, the involvement of Janssen UK and of UK health professionals meant that Janssens UK had responsibilities under Clause 8.2. On the basis of all of these factors, the Panel **ruled a breach of Clause 8.2**.

Clause 10.1

The Panel did not think that Beigene had provided any evidence to support its allegation that Janssen had failed in its obligation to remind its affiliate (JPNV) that the ABPI Code must be complied with where UK health professionals attend events which JPNV organise abroad.

Beigene had the burden of proving a breach of Clause 10.1 on the balance of probabilities and the content of its complaint had failed to do that. On that basis the Panel **ruled no breach of Clause 10.1**.

Clauses 2, 3.4 and 5.1

Given the nature of the breach of Clause 8.2 was that there was a failure to certify slides (and not that there was necessarily anything in those slides that was not Code-compliant), the Panel did not consider this to be a breach of Clauses 2, 3.4 and 5.1.

Beigene had not made out its case on what specifically was the alleged breach of Clause 3.4. In addition, they had provided no evidence to show that there was a wider failure on the part of Janssen to maintain high standards (Clause 5.1).

In other words, this complaint did not attempt to show that this was a widespread issue. On the basis of the evidence provided to it by both parties, the Panel was satisfied that this appeared to be a one-off incident and that a single ruling of a breach of Clause 8.2 was sufficient in relation to this matter.

The Panel considered Clause 2 in particular to be reserved for censure in cases where the breaches are of a particularly serious or systemic nature. The Panel did not consider that to be the case here and therefore **ruled no breach of Clauses 2, 3.4 and 5.1**.

APPEAL BY JANSSEN

Janssen appealed the Panel's ruling of a breach of Clause 8.2.

Janssen's written basis for appealing is reproduced below:

> "The complaint relates to a symposium sponsored by Janssen's European organisation - Janssen Pharmaceuticals ("JPNV") at the European Haematology Association (EHA) conference hosted in Frankfurt on 8th June 2023. Janssen notified the PMCPA of the intent to appeal the ruling on the 11th of November, the reasons for that appeal are as follows. Please be aware that as of May 2024, Janssen has undergone a rebranding, and the pharmaceutical division is now called Johnson and Johnson Innovative Medicine. For the sake of consistency, Janssen is used throughout this letter because the complaint was made before the rebranding occurred.
>
> Janssen do not agree with the PMCPA's ruling and the assertion that the presentation at issue, given by a UK speaker but arranged and contracted by Janssen's European organisation, is subject to the ABPI Code of Practice such that it required certification. The ruling appears to hinge on the interpretation of the supplementary information to Clause 8.2 of the Code of Practice. We contend that this supplementary guidance is relevant only when UK speaker services are arranged through a UK company, and when the presentation is promotional; neither of which was the case here.
>
> Whilst Janssen does not believe that the presentation at issue is within scope of Clause 8.2 of the ABPI Code, if the appeal board upholds the panel's ruling, then the ruling must clarify exactly what aspects of the arrangements bring it within scope. This is important because if the current, broad interpretation of Clause 8.2 provided to us by the PMCPA is applied going forwards, UK companies will be taking a significantly different approach to that required in other EFPIA countries.
>
> We would like to address the four factors considered by the panel, including the implications for UK participation in international congresses:
>
> **1.Applicability of Supplementary Information**
> The supplementary information to Clause 8.2 ("**Clause 8.2 Presentations by UK Speakers at Events/Meetings Held Outside the UK**" states:
> *When a pharmaceutical company based outside the UK **arranges via a UK company** for a UK speaker to present at an event/meeting to be held outside the UK, then that speaker's presentation materials do not need to be certified or examined by the UK, provided there are no UK delegates and the UK company has no role whatsoever in relation to the event/meeting or the presentation. In such circumstances, the*

event/meeting arrangements, in as much as they apply to the UK speaker, will not have to be certified or examined.

We have highlighted a specific aspect of this paragraph – that which clearly states the UK company is involved in the booking of the speaker.

The service provision arrangements in this case were as follows; the UK speaker was selected, contracted, and compensated by Janssen's European organisation, with Janssen UK not being involved with either the selection or the arrangements of the speaker's service provision. The supplementary information to Clause 8.2 clearly states that it applies when arrangements for a speaker to present are made via a UK company which does not reflect the circumstances in question.

It is noteworthy that there was a recent similar case (AUTH/3746/2/23), published in August 2024 which was also ruled in breach. The key difference however between the two cases lies in the fact that in case AUTH/3746/2/23, the UK speaker was directly contracted by the UK organisation and UK HCPs in attendance at the meeting were directed to attend a promotional presentation through the distribution of flyers on the company promotional stand. Neither of these factors apply in Janssen's case.

2. Facilitation of Attendance
The provision of the services of the speaker in question were facilitated and arranged through Janssen Europe, they were not arranged via Janssen UK.

Janssen UK approved the travel for the speaker in compliance with the guidelines outlined in Clause 8.2 ("**Clause 8.2 Events/Meetings Involving Travel Outside the UK**"), but it is essential to clarify that Janssen UK only supported the speaker's attendance as a delegate to the conference.

This support is distinct from the arrangements made for the speaker's services, which were managed independently by Janssen Europe. Support of healthcare professionals to attend international congresses is rightly provided such that it is completely independent of all commercial considerations and promotional activity. We do not believe that providing such support should bring with it further obligations to approve presentation materials and we believe that any suggestion that this is the case would be contradictory.

3. Certification of Slides
Janssen UK confirmed that it did not certify the presenter's slides.

In addition to our observations above regarding the applicability of the supplementary information to Clause 8.2 (**"Clause 8.2 Presentations by UK Speakers at Events/Meetings Held Outside the UK")**, we also wish to clarify the nature of the event.

Clause 8.1 clearly states that promotional material (such as slides) requires certification. Non-promotional material is not in scope of Clause 8.1.

Long standing convention is that the applicable Code for any activity is that of the host nation unless something specific brings that activity into the scope of the UK's ABPI Code. It is a well-founded principle that materials, such as stand materials, are not required to undergo individual certification by all countries represented at an event, but rather that

approval be coordinated by the country where the event is held. Indeed, in relation to the applicability of different countries' codes of practice, the supplementary information to Clause 1.1 recognizes that promotional material distributed at events must comply with **local** requirements.

The host nation and the Janssen regional team regarded this event as non-promotional medical education. As the Appeal Board is aware, the UK is relatively unique in its failure to apply Article 17 of the EFPIA Code (Life-Long Learning in Healthcare). The host nation clearly classified this event as most symposia at major conferences are classified, as non-promotional medical education. As such, Janssen UK could not Certify the event as promotional, because in doing so it would have undermined the legitimacy of the event in the host nation.

Janssen remain committed to complying with the requirements of the Code of Practice both in spirit and in letter, as demonstrated by the review and approval of the UK speaker arrangements and the support provided to UK HCPs in accordance with Clause 8.2 (“**Clause 8.2 Events/Meetings Involving Travel Outside the UK”).**

However, when a UK operating company has not selected or contracted a UK speaker for the delivery of a presentation which will take place outside of the UK, and no UK HCPs are directed to, or invited to attend that presentation by the UK company, we maintain that certification of their slides by Janssen UK is unnecessary. We believe that our understanding aligns with interpretations held by other member companies.

Regardless, if Janssen is to be ruled in breach of the Code for a failure to certify promotional slides, we contend that the appropriate clause to apply is 8.1. Clause 8.2 is specific to the meeting *arrangements*, not the promotional materials displayed at the event.

4. Presence of UK Delegates

It is reasonable to expect UK delegates at major international conferences, even if not supported by a UK company. The ruling implies that if a pharmaceutical company outside of the UK engages a UK speaker, the UK affiliate must certify the speaker's slides. Janssen UK accepts that if a UK company directs or invites UK delegates to attend a promotional symposium outside of the UK, then the ABPI Code applies to presentations that the UK HCP will be exposed to during that symposium, however in the current case, Janssen UK did not direct or invite any UK delegates to the symposium in question.

If there is a concern about what information UK delegates may hear at company sponsored symposia taking place outside of the UK, then surely all presentations, irrespective of the nationality of the speaker, should be approved under the ABPI Code or UK delegates should be actively excluded from such events. That would clearly be a significant precedent, setting a different standard for UK congress attendees than is required for attendees from other EFPIA countries.

The implication of the current ruling is likely to be a reduction in the number of UK experts speaking at such events, or the necessity to implement additional controls to restrict UK conference delegates from attending industry-sponsored symposia—both of which contradict the UK life sciences strategy and the ambitions of the UK medical and scientific community.

Conclusion
The PMCPA ruling seems to connect several independent observations across the distinct activities of delegate support and service provision, and Certification, applying them to an interpretation of the supplementary information to Clause 8.2 such that Clause 8.1 applies, yet ruling is in breach of Clause 8.2. Janssen believes that the factors considered in arriving at this decision have not been sufficiently considered or clarified, raising concerns that it may set a precedent adversely affecting the UK's standing on the international stage.

We respectfully request a re-evaluation of the ruling, taking into account the nuanced circumstances presented and considering the broader impact of such a decision on the industry as a whole.

Thank you for your attention to this matter."

RESPONSE FROM BEIGENE

There was no response from BeiGene.

APPEAL BOARD RULING

As part of its appeal, Janssen accepted that Janssen UK had arranged and paid for the speaker (and nine other UK health professionals) to attend the conference in Frankfurt as an attendee. Janssen submitted it had certified the travel and other arrangements for those health professionals under Clause 8.2 of the Code.

At that conference, the speaker had presented slides as part of a symposium organised by Janssen Europe. The Panel had ruled a breach of Clause 8.2 because Janssen UK had not certified those slides. The Panel had relied primarily on the section of the supplementary information to Clause 8.2, titled "*Presentations by UK Speakers at Events/Meetings Held Outside the UK*". That supplementary information states:

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

The subclauses of Clause 8 deal with certification and examination in various contexts, including promotional material (8.1), event/meetings involving travel outside the UK (8.2), and various types of non-promotional material (8.3). Clause 8.5 sets out what needs to be considered by the signatory under various sub clauses within Clause 8. In relation to Clause 8.2, Clause 8.5 says that 'the certificate for events/meetings involving travel outside the UK must certify that the signatory has examined all the proposed ***arrangements*** and that, in their belief, they are in accordance with the relevant regulations relating to advertising and the Code [emphasis added]'. The word 'materials' appears in various subclauses, but does not appear in Clause 8.2. The Appeal Board also noted that Clause 8.2, unlike Clauses 8.1 and 8.3, did not require certification by a signatory that was a registered medical practitioner or pharmacist

registered in the UK, but by an appropriately qualified person signatory. In the light of all of those observations, the Appeal Board determined that Clause 8.2 did not extend to certification of speaker's materials. Such materials may fall to be certified under Clause 8.1 or 8.3 in certain situations.

The Appeal Board considered the section of the supplementary information which the Panel had relied on. The Appeal Board took the view that supplementary information was intended to clarify the Clause, but that the wording of the Clause took precedence; the supplementary information was therefore not relied on by the Appeal Board as indicating that Clause 8.2 applied to speaker's materials.

The Appeal therefore succeeded on the basis that Janssen appeared to have appropriately certified arrangements for the meeting as required by Clause 8.2, and the lack of certification of speaker's materials did not put Janssen in breach of Clause 8.2. In some circumstances, speaker's materials are required to be certified under other clauses, such as Clause 8.1, but other clauses were not before the Appeal Board, and so the Appeal Board did not rule on whether other clauses might be engaged.

Janssen's appeal on this point was successful.

Complaint received **18 September 2023**

Case completed **22 January 2025**