CASE AUTH/3250/10/19

LILLY/DIRECTOR v JANSSEN

Pre-licence promotion and breach of undertaking

Eli Lilly & Company alleged that Janssen-Cilag promoted Tremfya (guselkumab) for use in psoriatic arthritis (PsA) at an event entitled 'Pipelines in Psoriatic Arthritis' at the British Society of Rheumatology (BSR) Annual Conference. Tremfya was indicated for the treatment of moderate to severe plaque psoriasis in adults who were candidates for systemic therapy.

As Lilly's complaint also included an alleged breach of undertaking, that part of the complaint was taken up by the Director as the Authority itself was responsible for ensuring compliance with undertakings.

Lilly noted that guselkumab data was presented at the event in the context of a presentation which concluded that 'novel treatments have demonstrated favourable efficacy and safety profiles in placebo-controlled trials'.

Lilly stated that the legitimate exchange of medical and scientific information must be a two-way exchange of information which enhanced the current state of knowledge of both the company and the audience. Sufficient time must be set aside for this exchange, and sufficient attempt made to stimulate questioning by the audience. In this case, a very small proportion of the overall session was set aside for an abbreviated closing questions and answers session, and only two questions were asked. This was inevitably the case given that the speaker presented 63 slides.

Attendees were encouraged to fill out an evaluation form, which included an invitation to ask for 'further information on the topics discussed during this meeting'. The Janssen booth at the conference included a commercial section and a medical information section with staff on hand to provide information on off-label indications and pipeline products. In Lilly's view, it was reasonable to assume that a number of booth visitors would ask about guselkumab, and that Janssen appeared to be soliciting questions about its unlicensed medicine.

Lilly noted that the innovation session was a silent session conducted in a non-segregated area in close vicinity to multiple exhibition stands; delegates wore headsets to block out background noise and to guarantee that they could hear the speaker. The slides were projected on a large screen, which was clearly visible to non-attendees of the session including people visiting exhibition stands. In Lilly's view, these arrangements were incompatible with Code requirements for the legitimate exchange of medical and scientific information.

Lilly alleged that the Janssen-sponsored session was in breach of the Code and that the number and nature of the breaches identified meant that Janssen had brought discredit upon, and reduced confidence in, the pharmaceutical industry.

Lilly noted that Janssen was found to have promoted an unlicensed medicine and to have brought the industry into disrepute in Case AUTH/2978/9/17 in circumstances very similar to those described above. Repeated breaches of this nature undermined confidence in self-regulation and threatened patient safety.

The detailed response from Janssen is given below.

The Panel noted Janssen's submission that at the time of the innovation session (1 May 2019), Tremfya was approved for the treatment of moderate to severe plaque psoriasis in adults who were candidates for systemic therapy; it was not approved for PsA and Phase III studies were on-going. No submission for a licence in PsA had been made anywhere globally. A European Medicines Authority (EMA) submission for PsA was subsequently made on 11 October 2019 with expected approval in September 2020. The Panel noted that guselkumab was already available for the treatment of moderate to severe plaque psoriasis in certain patients. The Panel considered that it was not necessarily unacceptable for such products to be the subject of legitimate exchange of scientific and medical information in relation to its unlicensed use but companies should be especially cautious when so doing and would have to establish that the medicine was in development in relation to the subject matter of the legitimate exchange. All of the circumstances would be relevant when deciding whether such activity was appropriate.

The Panel queried whether Janssen's submission, that it was not aware that the purpose-built theatre was not in a segregated area until the day of the innovation session, was entirely correct given that the BSR packages 2020 brochure detailing the sponsorship and contribution opportunities for companies and provided by Janssen stated that the 'open plan innovation theatre within the exhibition hall' provided a timeslot for exhibiting companies to educate attendees during the breaks. The Panel noted, however, that the brochure also referred to not being able to provide catering 'inside the theatre' and that a catering point would be placed near the entrance to the theatre which might imply that it was a closed venue. Whilst open plan was not defined and there did not appear to be a proposed plan of the exhibition hall, the Panel queried whether Janssen ought to have made further queries in this regard.

The Panel noted the BSR packages brochure stated that symposia sessions were permitted to be promotional and that innovation theatre sessions were perfect for demonstrations and short presentations and that the open plan innovation theatre within the exhibition hall provided a timeslot for exhibiting companies to educate attendees during the breaks and queried whether these descriptions were conducive to the legitimate exchange of scientific information. The Panel noted that all meetings, including promotional meetings, had to be educational. In any event, context was important and presentation of otherwise non-promotional material in a promotional context could render such non-promotional material promotional. The Panel noted BSR's requirement that innovation sessions were not permitted to be promotional and queried whether this would give rise to difficulties for companies given the open plan innovation theatre was part of the exhibition hall which was generally considered to be a promotional area.

The Panel noted Janssen's submission that whilst some slides might have been visible to non-attendees of the innovative session, they would not have been clearly legible given the size of the hall. In the Panel's view, meetings for the legitimate exchange of

medical and scientific information during the development of a medicine were better suited to closed sessions.

The Panel noted Janssen's submission that it did not proactively invite delegates to the innovation session; delegates attended the session of their own accord based on the information available in the BSR delegate materials. The Panel queried whether the company could be confident that all delegates (170) were each able to meaningfully contribute to a discussion that enhanced the current state of scientific knowledge.

The Panel noted that the innovation session ran for 40 minutes and consisted of a five-minute welcome and introduction followed by a 20 minute presentation on 'Pipelines in PsA' followed by 15 minute Q&A and discussion. The Panel queried whether the 63 sides could have been properly presented within 20 minutes thus leaving the allotted time for Q&As and whether this was one reason why there had been little group discussion. The introduction slide stated that the session was about scientific exchange and encouraged the audience to ask lots of questions at the end. The Panel noted Janssen's submission that it had intended for more questions and open discussion but despite the measures put in place, there were fewer questions than anticipated. Despite encouragement, according to Janssen, only two main questions were discussed at the end of the session as well as multiple questions directed to the speaker on a one-on-one basis once the session had closed. The Panel noted Janssen's submission that using digital means to encourage discussion was not possible at the venue and it would continue to explore how audience engagement could be increased in future sessions. The Panel considered that there was very little evidence of any legitimate scientific exchange.

The Panel noted that the first page of the speaker briefing described the 'Meeting rationale and objectives' as to establish the drug classes currently explored in this area and how their mechanisms of action function in relation to the pathophysiology of PsA and to further understanding of the pathways currently being targeted in PsA to provide context to the PsA treatment pipeline. The stated objectives implied that data was being presented. This was followed by logistical details and presentations: general guidance. The first mention that the aim of the presentation was to facilitate the exchange of scientific and medical information was the first bullet point under the general guidance for presentations. Page 3 of the speaker's brief 'Specific guidance on presentation key points' also advised the speaker at the outset to ask attendees to participate in the discussion. The objective of the Q&A and discussion with delegates section was stated to be to facilitate scientific exchange, discussion and engagement around the session's content.

In addition, the Panel noted that an email to the speaker in late April stated that the key aim of the session was to provide a balanced overview of all treatments currently in development for PsA. It referred to allowing plenty of time for discussion but made no mention of medical and scientific exchange that enhanced the current state of scientific knowledge.

The Panel noted Janssen's submission that the speaker presented data on several molecules in development in a fair and balanced manner and did not place any emphasis on guselkumab trial data; of the 63 slides presented 3 were on guselkumab and 2-4 slides each on the other 6 development molecules from other companies. According to

Janssen, the analysis of the trial data followed the same format for each of the investigational medicines with the intent to convey the progress of the medicines in development as per the objective of the session and guselkumab was presented no differently in this regard.

The Panel noted that the presentation discussed 7 compounds in development for PsA, guselkumab was the fourth compound discussed, on four slides (1 title slide and 3 detailed slides). The last guselkumab slide included a grey square entitled 'Conclusions' which stated 'GUS demonstrated robust efficacy for the treatment of cutaneous manifestations of psoriasis in patients with PsA and ≥3%BSA. Responses were maintained through Week 56' and 'Treatment with GUS produces rapid and sustained improvement in enthesitis in patients with active PsA, correlating with improvements in joint symptoms'. Slides for four of the seven compounds included such a conclusion section. In the Panel's view, the conclusion section for guselkumab could be considered to be claims for the product.

The Panel further noted that the summary slide included three bullet points namely: 'Multiple treatments are currently available for the treatment of PsA, but there is still an unmet need as many patients experience significant disability and impaired quality of life'; 'Novel treatments in Phase II and Phase III trials for PsA span the following MoAs:' and included IL-23 inhibitors: guselkumab, risankizumab and tildrakizumab as one of the three class examples; and 'Novel treatments have demonstrated favourable efficacy and safety profiles in placebo-controlled trials'. The Panel noted Janssen's submission that the last bullet point was referenced by the speaker with brodalumab and risankizumab trials with the intention of highlighting that clinical trial results across all investigational medicines in PsA suggested that the mechanisms of actions of these medicines had potential in the treatment of PsA. In the Panel's view, the summary slide referred to all of the potential PsA treatments including guselkumab. In the Panel's view, the presentation did not overall give disproportionate emphasis to guselkumab.

The Panel noted that the evaluation form invited attendees to ask for further information on the topics discussed during this meeting. The Panel considered that the presentation was likely to raise interest in relation to all of the products referred to including Janssen's guselkumab and thus it might be argued that Janssen was soliciting questions about its unlicensed medicine. The Janssen BSR briefing included on the slide about the innovation session that if any customers proactively asked about the session, they should be referred to the MSL.

In the Panel's view, it was reasonable to assume that, on the balance of probabilities, attendees might ask about guselkumab. The briefing materials prepared staff for such questions and medical information staff were available to answer such questions.

The Panel noted Janssen's submission that the medical information stand within the exhibition hall was unbranded with no mention of pipeline or investigational molecules and there was no data relating to guselkumab available on it. The Janssen promotional booth was for Stelara (ustekinumab) in PsA only (approved indication) and there was no mention of guselkumab anywhere on the stand. The briefing for Janssen representatives clearly stated not to discuss IL-23 and refer to medical if any queries were received. Staff were asked to walk the customer over to the separate medical stand. The Panel,

however, noted Janssen's submission that no requests for further information were made following the innovation session either on the form or directly to any Janssen staff.

The Panel noted its comments above and queried whether the arrangements for the presentation were conducive to the legitimate exchange of scientific information during the development of a medicine. In the Panel's view, the cumulative effect of the large number of slides presented within a short period of time, the lack of discussion, the inappropriate venue, concerns about the speaker's briefing and the question mark over whether all 170 attendees were appropriate given the need to contribute to scientific debate was such that, on balance, the meeting was not the legitimate exchange of scientific and medical information. The Panel also noted, what it considered, on balance, to be the promotional nature of the guselkumab conclusion slide and the summary slide. The Panel noted its comments above that the meeting did not constitute legitimate exchange of medical and scientific information and therefore could not take the benefit of the relevant supplementary information. The Panel noted that the meeting discussed the unlicensed use of guselkumab for PsA and, in the Panel's view, promoted it for an unlicensed indication. The Panel ruled a breach of the Code. The Panel considered that high standards had not been maintained: insufficient enquiries about the presentation space were made at the outset and a decision was made to go ahead on the day of the meeting when the layout of the exhibition hall was clear, and inadequate instruction had been given to the speaker about the requirements for scientific exchange. A breach of the Code was ruled.

The Panel noted that promotion of an unlicensed medicine was an example of an activity likely to be in breach of Clause 2. The Panel considered that Janssen had brought discredit upon, and reduced confidence in, the pharmaceutical industry and, on balance, ruled a breach of Clause 2 of the Code.

The Panel noted that in Case AUTH/2978/9/17 Janssen was ruled in breach of Clause 3.1 for promoting guselkumab prior to the grant of its marketing authorisation. There were important differences between the two cases. In Case AUTH/2978/9/17, unlike the present case, the product in question was shortly to receive its marketing authorisation, the presentation focussed solely on the product in question and it appeared that the presentation in question was part of a meeting that included a separate promotional presentation about Janssen's product Stelara. The Panel noted that there were, nonetheless, important similarities including that there was little discussion. The Panel noted that the nature and depth of discussion was fundamental to the legitimate exchange of medical and scientific information. Noting the latter point and its comments and rulings above, in the present case, the Panel considered that, on balance, Janssen had failed to comply with its undertaking given in Case AUTH/2978/9/17 and a breach of of the Code was ruled. The Panel considered that Janssen's breach of undertaking meant that it had failed to maintain high standards on this point and brought discredit upon, and reduced confidence in, the pharmaceutical industry and breaches of the Code including Clause 2 were ruled.

Eli Lilly and Company Limited alleged that Janssen-Cilag Limited promoted Tremfya (guselkumab) for use in psoriatic arthritis (PsA) at an event at the British Society of Rheumatology (BSR) Annual Conference. Tremfya was indicated for the treatment of moderate to severe plaque psoriasis in adults who were candidates for systemic therapy.

As Lilly's complaint also included an alleged breach of undertaking, that part of the complaint was taken up by the Director as the Authority itself was responsible for ensuring compliance with undertakings.

COMPLAINT

Lilly noted that on 1 May 2019, Janssen sponsored an event entitled 'Pipelines in Psoriatic Arthritis' at the BSR Annual Conference. The event had the following stated objectives:

> 'Aim: To further understanding of the pathways currently being targeted in PsA to provide context to the PsA treatment pipeline.
>
> Outcome 1: To establish the drug classes currently being explored in this area and how their mechanism of action function in relation to the pathophysiology of PsA.
>
> Outcome 2: To further understanding of the pathways currently being targeted in PsA to provide context to the PsA treatment pipeline.'

Several Lilly employees attended the event, and Lilly's account of the content and arrangements of the event was based on their direct experience.

Guselkumab data was presented at the event. It was presented in the context of a presentation which concluded that 'novel treatments have demonstrated favourable efficacy and safety profiles in placebo-controlled trials'.

Lilly noted that Clause 3.1 stated that a medicine must not be promoted prior to the grant of its marketing organization. An exception for the legitimate exchange of medical and scientific information was permitted in certain specific circumstances provided it did not constitute promotion.

Lilly submitted that legitimate exchange of medical and scientific information must be a two-way exchange of information which enhanced the current state of knowledge of both the company and the audience. Sufficient time must be set aside for this exchange, and sufficient attempt made to stimulate questioning by the audience. In this case, a very small proportion of the overall session was set aside for an abbreviated closing questions and answers session, and only two questions were asked. This was inevitably the case given that the speaker presented 63 slides.

At the end of the session attendees were encouraged to fill out an evaluation form, which included an invitation to ask for 'further information on the topics discussed during this meeting'. The Janssen booth at the conference included a commercial section and a medical information section with staff on hand to provide information on off-label indications and a pipeline information section with staff on hand to provide information on off-label indications and pipeline products. In Lilly's view, it was reasonable to assume that a number of booth visitors would ask about guselkumab, and that Janssen appeared to be soliciting questions about its unlicensed medicine.

The innovation session was a silent session conducted in a non-segregated area in close vicinity to multiple exhibition stands; delegates wore headsets to block out the noise from the bustling exhibition hall and to guarantee that they could hear the speaker. The slides were

projected on a large screen, which was clearly visible to non-attendees of the session including people visiting exhibition stands. In Lilly's view, these arrangements were incompatible with Code requirements for the legitimate exchange of medical and scientific information.

In summary, Lilly alleged that the Janssen-sponsored session 'Pipelines in Psoriatic Arthritis' was in breach of Clause 3.1. Furthermore, Lilly considered that the number and nature of the breaches identified meant that Janssen had brought discredit upon, and reduced confidence in, the pharmaceutical industry contrary to Clauses 9.1 and 2 of the Code.

Lilly noted that Janssen was found to have promoted an unlicensed medicine and to have brought the industry into disrepute in Case AUTH/2978/9/17 in circumstances very similar to those described above. Lilly alleged that repeated breaches of this nature undermined confidence in self-regulation and threatened patient safety.

When writing to Janssen, the Authority asked it to consider the requirements of Clauses 2, 9.1 and 29 of the Code in relation to the alleged breach of undertaking and, in addition, the requirements of the clauses of the Code cited by Lilly in relation to the event at issue.

RESPONSE

Janssen explained that the BSR Annual Conference held in the UK gave rheumatology professionals an opportunity to learn about the latest developments in the therapy area from experts in the field. Companies could contribute to the programme through symposia sessions, which could be promotional and innovation sessions which had to be educational. An innovation session was delivered in a purpose-built theatre within the exhibition hall. The attendees listened to the presentation through headsets. Question and answer (Q&A) sessions were possible with innovation sessions, but panel Q&A was not.

Janssen did not proactively invite delegates to the innovation session. Details of the innovation session were found on the conference app which was wholly controlled by the BSR. The BSR used the content from the speaker briefing document. In addition, flyers were placed on the seats in the purpose-built theatre and a banner was displayed in the venue at the start of the session. Delegates attended the session of their own accord based on the information available in the delegate app and the overall programme which they received from the BSR on arrival. The sales force was briefed not to discuss the session with any health professionals and if they were asked about the session, they were directed to refer the enquiries to a medical science liaison (MSL).

At the time of the innovation session, Tremfya was approved for the treatment of moderate to severe plaque psoriasis in adults who were candidates for systemic therapy; it was not approved for PsA and Phase III studies were on-going (DISCOVER 1 and DISCOVER 2 trials). No submission for a licence in PsA had been made anywhere globally. A European Medicines Authority (EMA) submission for PsA was made on 11 October 2019 with expected approval September 2020. Submission for approval by the National Institute for health and Care Excellence (NICE) had not been made and the base case for NICE reimbursement was March 2021. Janssen did not have any other molecules in development for the treatment of PsA. As the session in question was non-promotional, no prescribing information was available at the meeting.

Janssen Medical Affairs had organised the innovation session in conjunction with an eminent expert in PsA to enable legitimate scientific and medical exchange in a disease area where extensive research and development was on-going to fulfil an unmet need. The content of the presentation was developed at the discretion of the speaker. The statement 'Novel treatments have demonstrated favourable efficacy and safety profiles in placebo-controlled trials' was referenced by the speaker with brodalumab and risankizumab trials with the intention of highlighting that clinical trial results across all investigational medicines in PsA suggested that the mechanisms of actions of these medicines had potential in the treatment of PsA.

Janssen submitted that following several briefings, the speaker presented data on several molecules in development in a fair and balanced manner and did not place an emphasis on guselkumab trial data. Of the 63 slides presented, there were 3 on guselkumab and 2-4 slides on the other 6 development molecules from other companies. The analysis of the trial data followed the same format for each of the investigational medicines with the intent to convey the progress of the medicines in development as per the objective of the session. Guselkumab was presented no differently in this regard.

The agenda clearly listed 15 minutes for Q&A and discussion, ie 37.5% of the total session. Janssen rejected Lily's allegation that only a very small proportion of the overall session was set aside for an abbreviated closing Q&A.

There were three slides presented which demonstrated the intent to invite questions and stimulate debate:

- Slide 4 – 'Questions will be taken after the presentation'.
- Slide 5 – 'There will be 15 minutes for discussion at the end of the session and I encourage you all to ask lots of questions'.
- Slide 62 – 'Discussion and Q&A' section clearly signposted.

The speaker briefing also highlighted in the agenda 15 minutes for 'All' 'Q&A and discussion' and specified:

> 'This meeting is non-promotional and aims to facilitate the exchange of scientific and medical information. We ask that speakers give a fair and balanced interpretation and analysis of data.'

The briefing document also clearly stated:

> '11:05-11:20 - All, Format: Q&A and discussion with delegates; Objective: To facilitate scientific exchange, discussion and engagement around the session content.'

Janssen stated that it also followed up with the speaker on 25 April 2019 in addition to the briefing document which highlighted '15 minutes for Q&A and discussion'. This point was also highlighted on briefing calls before the event. Of the 63 slides presented on the day, 18 were title or housekeeping slides. A reduced content would not have allowed the speaker to provide a fair and balanced overview of the breadth of development activity in PsA.

Two main questions were discussed at the end of the session as well as multiple questions directed to the speaker on a one-on-one basis once the session had closed. Janssen had intended for more questions and open discussion but despite the measures put in place as

described above, there were fewer questions than anticipated. Janssen explored the option of using digital means to encourage questions and discussion but this functionality was not possible at the venue.

Janssen believed enough efforts were made to encourage scientific exchange and it did not consider that having two questions asked at the end of the session equated to a one-way flow of information. Janssen would continue to explore how engagement from the audience could be increased in future sessions.

Janssen noted that the evaluation form stated:

> 'If you would like to have further information on the topics discussed during this meeting, please let us know the nature of your requests below and provide an email address or contact telephone number so that a member of the Janssen Medical Affairs department can contact you. Your email address/phone number would only be used for that purpose.'

This was intended to provide an avenue for queries for those who wanted to follow up with questions on the session later. These questions would only be seen by the medical affairs department which would reactively provide non-promotional information to health professional if they required any specific information. No requests for further information were made following the innovation session either on the form or directly to any Janssen staff.

Whilst Janssen did not consider this option on an evaluation form about a non-promotional, legitimate scientific and medical exchange session equated to soliciting questions on an unlicensed medicine, it would omit such questions from future feedback forms.

The medical information stand in the exhibition hall was unbranded with no mention of pipeline or investigational molecules nor was there any data relating to guselkumab available on it. The Janssen booth at the congress was for Stelara (ustekinumab) in PsA only (approved indication) and there was no mention or content of guselkumab anywhere on this stand. The briefing for Janssen representatives clearly stated not to discuss IL-23 and refer to medical if any queries were received.

Janssen submitted that, as stated above, an innovation session at the BSR was delivered in a purpose-built theatre within the exhibition hall which was designated by the BSR. Janssen did not know that the purpose-built theatre was not in a segregated area until the day of the innovation session. Janssen acknowledged that the venue was not ideal for this session given the surrounding activities and noise, but no other venues were available at the conference. Whilst some slides might have been visible to non-attendees, they would not have been clearly legible given the size of the hall and, in Janssen's view, this was not incompatible with the requirements for the legitimate exchange of scientific and medical information. On balance, Janssen considered that it would be reasonable to proceed with the session as planned – it had already agreed to address the suitability of the venue with the BSR for future sessions (on behalf of all companies).

Janssen noted that 44 of 170 attendees completed the evaluation form; 95% of the respondents rated the innovation session as 'very good' or 'excellent' with regards to overall interest. Ninety eight per cent considered that it had either met or exceeded expectations. Janssen believed, as did the audience, that the meeting was of high educational value.

With regards to Case AUTH/2978/9/17, Janssen considered that there were several areas where it had demonstrated learnings from that ruling. It was clearly mentioned to both the speaker (via briefings) and to the audience that a key objective of the session was scientific exchange and questions were encouraged. Guselkumab did not feature prominently in the presentation and no prescribing information was available. The evaluation form did not ask whether the session 'could change your clinical practice' which was used on the form referred to in Case AUTH/2978/9/17. Furthermore, no marketing authorisation had been sought for the PsA indication anywhere in the world at the time of the session. Janssen considered that all possible steps had been taken to avoid similar breaches found in Case AUTH/2978/9/17.

In summary, Janssen considered the innovation session was accurate, balanced, up-to-date, appropriate and non-promotional and it denied breaches of Clauses 2, 3.1, 9.1 and 29 of the Code.

PANEL RULING

The Panel noted the broad definition of promotion at Clause 1.2 of the Code. The Panel also noted that although Clause 3 prohibited the promotion of a medicine prior to the grant of its marketing authorization, the Code permitted companies to undertake certain activities with regard to unlicensed medicines. The supplementary information to Clause 3 provided additional details including a statement that the legitimate exchange of medical and scientific information during the development of a medicine was not prohibited provided that this did not constitute promotion which was prohibited by Clause 3 or any other clause. The PMCPA Guidance about Clause 3 provided informal guidance stating that companies must ensure that such activities constituted a genuine exchange of information and were not promotional. The legitimate exchange of scientific information during the development of a medicine should involve debate that enhanced the current state of scientific knowledge. To avoid being seen as promotional, it should not be a one way flow of information.

The Panel noted Janssen's submission that at the time of the innovation session (1 May 2019), Tremfya was approved for the treatment of moderate to severe plaque psoriasis in adults who were candidates for systemic therapy; it was not approved for PsA and Phase III studies were on-going (DISCOVER 1 and DISCOVER 2 trials). No submission for a licence in PsA had been made anywhere globally. A European Medicines Authority (EMA) submission for PsA was subsequently made on 11 October 2019 with expected approval in September 2020. The Panel noted that guselkumab was already available for the treatment of moderate to severe plaque psoriasis in certain patients. The Panel considered that it was not necessarily unacceptable for such products to be the subject of legitimate exchange of scientific and medical information in relation to its unlicensed use but companies should be especially cautious when so doing and would have to establish that the medicine was in development in relation to the subject matter of the legitimate exchange. All of the circumstances would be relevant when deciding whether such activity was appropriate.

The Panel queried whether Janssen's submission, that it was not aware that the purpose-built theatre was not in a segregated area until the day of the innovation session, was entirely correct given that the BSR packages 2020 brochure detailing the sponsorship and contribution opportunities for companies and provided by Janssen stated that the 'open plan innovation theatre within the exhibition hall' provided a timeslot for exhibiting companies to educate attendees during the breaks. The Panel noted, however, that the brochure also referred to not being able to provide catering 'inside the theatre' and that a catering point would be placed near

the entrance to the theatre which might imply that it was a closed venue. Whilst open plan was not defined and there did not appear to be a proposed plan of the exhibition hall, the Panel queried whether Janssen ought to have made further queries in this regard.

The Panel noted the BSR packages brochure stated that symposia sessions were permitted to be promotional and that innovation theatre sessions were perfect for demonstrations and short presentations and that the open plan innovation theatre within the exhibition hall provided a timeslot for exhibiting companies to educate attendees during the breaks and queried whether these descriptions were conducive to the legitimate exchange of scientific information. The Panel noted that all meetings, including promotional meetings, had to be educational. In any event, context was important and presentation of otherwise non-promotional material in a promotional context could render such non-promotional material promotional. The Panel noted BSR's requirement that innovation sessions were not permitted to be promotional and queried whether this would give rise to difficulties for companies given the open plan innovation theatre was part of the exhibition hall which was generally considered to be a promotional area.

The Panel noted Janssen's submission that whilst some slides might have been visible to non-attendees of the innovative session, they would not have been clearly legible given the size of the hall. In the Panel's view, meetings for the legitimate exchange of medical and scientific information were better suited to closed sessions.

The Panel noted Janssen's submission that it did not proactively invite delegates to the innovation session; delegates attended the session of their own accord based on the information available in the delegate app and the overall programme which they received from the BSR on arrival. The Panel further noted the number of attendees at the session (170) and queried whether the company could be confident that all delegates were each able to meaningfully contribute to a discussion that enhanced the current state of scientific knowledge.

The Panel noted that the innovation session at issue entitled 'Pipelines in PsA' started at 10:40 and consisted of a five-minute welcome and introduction followed by a presentation on 'Pipelines in PsA' (from 10:45 until 11:05). Fifteen minutes were then set aside for Q&A and discussion and the session finished at 11:20. The Panel noted that, according to Janssen, 63 slides were presented and queried whether this number of slides could have been properly presented within 20 minutes thus leaving the allotted time for Q&As and queried whether this was one reason why there had been little group discussion. The Panel noted that the introduction slide stated that the session was about scientific exchange and encouraged the audience to ask lots of questions at the end. The Panel noted Janssen's submission that it had intended for more questions and open discussion but despite the measures put in place, there were fewer questions than anticipated. The Panel noted that despite encouragement, according to Janssen, only two main questions were discussed at the end of the session as well as multiple questions directed to the speaker on a one-on-one basis once the session had closed. The Panel noted Janssen's submission that it had explored the option of using digital means to encourage discussion but this functionality was not possible at the venue and it would continue to explore how engagement from the audience could be increased in future sessions. The Panel considered that there was very little evidence of any legitimate scientific exchange.

The Panel noted that the first page of the speaker briefing described the 'Meeting rationale and objectives' as to establish the drug classes currently explored in this area and how their mechanisms of action function in relation to the pathophysiology of PsA and to further understanding of the pathways currently being targeted in PsA to provide context to the PsA

treatment pipeline. The stated objectives implied that data was being presented. This was followed by logistical details which, in turn, was followed by presentations: general guidance. The first mention that the aim of the presentation was to facilitate the exchange of scientific and medical information was the first bullet point under the general guidance for presentations. Page 3 of the speaker's brief 'Specific guidance on presentation key points' also advised the speaker at the outset to ask attendees to participate in the discussion. The objective of the Q&A and discussion with delegates section was stated to be to facilitate scientific exchange, discussion and engagement around the session's content.

In addition, the Panel noted that an email to the speaker dated 25 April stated that the key aim of the session was to provide a balanced overview of all treatments currently in development for PsA. It referred to allowing plenty of time for discussion but made no mention of medical and scientific exchange that enhanced the current state of scientific knowledge.

The Panel noted Janssen's submission that the speaker presented data on several molecules in development in a fair and balanced manner and did not place any emphasis on guselkumab trial data; of the 63 slides presented 3 were on guselkumab and 2-4 slides each on the other 6 development molecules from other companies. According to Janssen, the analysis of the trial data followed the same format for each of the investigational medicines with the intent to convey the progress of the medicines in development as per the objective of the session and guselkumab was presented no differently in this regard.

The Panel noted that the presentation discussed 7 compounds in development for PsA, guselkumab was the fourth compound discussed, on four slides (1 title slide and 3 detailed slides). The last guselkumab slide included a grey square entitled 'Conclusions' which stated 'GUS demonstrated robust efficacy for the treatment of cutaneous manifestations of psoriasis in patients with PsA and ≥3%BSA. Responses were maintained through Week 56' and 'Treatment with GUS produces rapid and sustained improvement in enthesitis in patients with active PsA, correlating with improvements in joint symptoms'. Slides for four of the seven compounds included such a conclusion section. In the Panel's view, the conclusion section for guselkumab could be considered to be claims for the product.

The Panel further noted that the summary slide included three bullet points namely: 'Multiple treatments are currently available for the treatment of PsA, but there is still an unmet need as many patients experience significant disability and impaired quality of life'; 'Novel treatments in Phase II and Phase III trials for PsA span the following MoAs:' and included IL-23 inhibitors: guselkumab, risankizumab and tildrakizumab as one of the three class examples; and 'Novel treatments have demonstrated favourable efficacy and safety profiles in placebo-controlled trials'. The Panel noted Janssen's submission that the last bullet point was referenced by the speaker with brodalumab and risankizumab trials with the intention of highlighting that clinical trial results across all investigational medicines in PsA suggested that the mechanisms of actions of these medicines had potential in the treatment of PsA. In the Panel's view, the summary slide referred to all of the potential PsA treatments including guselkumab. In the Panel's view, the presentation did not overall give disproportionate emphasis to guselkumab.

The Panel noted that the evaluation form invited attendees to ask for further information on the topics discussed during this meeting. The Panel considered that the presentation was likely to raise interest in relation to all of the products referred to including Janssen's guselkumab and thus it might be argued that Janssen was soliciting questions about its unlicensed medicine.

The Janssen BSR briefing included on the slide about the innovation session that if any customers proactively asked about the session, they should be referred to the MSL.

In the Panel's view, it was reasonable to assume that, on the balance of probabilities, attendees might ask about guselkumab. The briefing materials prepared staff for such questions and medical information staff were available to answer such questions. How to manage any questions regarding IL-23 was included as one of 5 main sessions on the agenda of the Janssen BSR briefing deck. It stated that any discussion of the use of Tremfya that was outside of its current licensed indication would be considered off-label and should be directed to the medical team onsite.

The Panel noted Janssen's submission that the medical information stand within the exhibition hall was unbranded with no mention of pipeline or investigational molecules and there was no data relating to guselkumab available on it. The Janssen promotional booth was for Stelara (ustekinumab) in PsA only (approved indication) and there was no mention of guselkumab anywhere on the stand. The briefing for Janssen representatives clearly stated not to discuss IL-23 and refer to medical if any queries were received. Staff were asked to walk the customer over to the separate medical stand. The Panel, however, noted Janssen's submission that no requests for further information were made following the innovation session either on the form or directly to any Janssen staff.

The Panel noted its comments above and queried whether the arrangements for the presentation were conducive to the legitimate exchange of scientific information during the development of a medicine. In the Panel's view, the cumulative effect of the large number of slides presented within a short period of time, the lack of discussion, the inappropriate venue, concerns about the speaker's briefing and the question mark over whether all 170 attendees were appropriate given the need to contribute to scientific debate was such that, on balance, the meeting was not the legitimate exchange of scientific and medical information. The Panel also noted, what it considered, on balance, to be the promotional nature of the guselkumab conclusion and summary slide. The Panel noted that Lilly had cited Clause 3.1 which prohibited the promotion of an unlicensed medicine and referred to the supplementary information to Clause 3 Marketing authorisation which mentioned the legitimate exchange of scientific and medical information. The Panel noted that guselkumab was not an unlicensed medicine and that its alleged promotion as a treatment for psoriatic arthritis, an unlicensed indication, would fall under Clause 3.2. The relevant supplementary information to Clause 3.2 made it clear that the promotion of indications not covered by the marketing authorisation for a medicine was prohibited by this clause. The Panel noted that whilst Lilly had apparently cited the incorrect clause, it had clearly described the subject matter of its complaint noting the indication for which it alleged guselkumab was promoted at the meeting in question and Janssen had responded in detail to the subject matter of the complaint. The subject matter of the allegation and response were mirrored in the inter-company dialogue. In such circumstances, the Panel considered that it was fair and appropriate to consider the matter raised and responded to under Clause 3.2. The supplementary information did not limit the requirements for legitimate exchange to Clause 3.1, although the Panel noted the relative difficulties of establishing that a medicine that already had a marketing authorisation was in development in relation to the unlicensed indication. Each case would be considered on its individual merits. In this regard, the Panel noted that Lilly had not alleged that guselkumab was not in development and the Panel therefore did not consider this point. The Panel noted its comments above that the meeting did not constitute legitimate exchange of medical and scientific information and therefore could not take the benefit of the relevant supplementary information. The Panel noted that the meeting discussed the

unlicensed use of guselkumab for PsA and, in the Panel's view, promoted it for an unlicensed indication. The Panel ruled a breach of Clause 3.2 of the Code. The Panel considered that high standards had not been maintained: insufficient enquiries about the presentation space were made at the outset and a decision was made to go ahead on the day of the meeting when the layout of the exhibition hall was clear, and inadequate instruction had been given to the speaker about the requirements for scientific exchange. A breach of Clause 9.1 was ruled.

The Panel note that promotion of an unlicensed medicine was an example of an activity likely to be in breach of Clause 2. The Panel considered that Janssen had brought discredit upon, and reduced confidence in, the pharmaceutical industry and, on balance, ruled a breach of Clause 2.

The Panel noted that in Case AUTH/2978/9/17 Janssen was ruled in breach of Clause 3.1 for promoting guselkumab prior to the grant of its marketing authorisation. The Panel noted that there were important differences between the present case and that considered previously in Case AUTH/2978/9/17. In Case AUTH/2978/9/17, unlike the present case, the product in question was shortly to receive its marketing authorisation, the presentation focussed solely on the product in question and it appeared that the presentation in question was part of a meeting that included a separate promotional presentation about Janssen's product Stelara. The Panel noted that there were, nonetheless, important similarities including that there was little discussion. The Panel noted that the nature and depth of discussion was fundamental to the legitimate exchange of medical and scientific information. Noting the latter point and its comments and rulings above, in the present case, the Panel considered that, on balance, Janssen had failed to comply with its undertaking given in Case AUTH/2978/9/17 and a breach of Clause 29 was ruled. The Panel considered that Janssen's breach of undertaking meant that it had failed to maintain high standards on this point and brought discredit upon, and reduced confidence in, the pharmaceutical industry and a breach of Clauses 9.1 and 2 was ruled.

Complaint received **4 October 2020**

Case completed **3 August 2020**