CASE AUTH/3213/6/19 ***NO BREACH OF THE CODE***

ANONYMOUS v JANSSEN

Alleged off-licence promotion

An anonymous, non-contactable complainant raised concerns about off-licence promotion which he/she alleged took place at a Janssen sponsored oncology meeting, held in March 2019.

Janssen marketed Zytiga (abiraterone) and Erleada (apalutamide) for use in the treatment of prostate cancer.

The complainant alleged that an external speaker who acted on behalf of Janssen, discussed 'off-licence' castrate resistant prostate cancer treatment. The complainant considered that the information was misleading and indirectly promotional and was therefore not appropriate for the meeting at issue which was advertised as a medical educational event. The content contained at least 7-10 slides of unlicensed information which was disseminated to a wide UK audience as well as broadcast via a webinar. The complainant stated that he/she felt misled and let down by this event.

The detailed response from Janssen is given below.

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure stated that anonymous complaints would be accepted, but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant could not be contacted for further information.

The Panel noted Janssen's submission that in the absence of more specific information it referred to the agenda for the live streamed component of the meeting and noted that two sessions in the morning addressed castrate resistant prostate cancer (CRPC): Treatment decisions for CRPC; and Optimising treatment for patients with metastatic CRPC. Janssen had reviewed the presentations in these sessions and could not identify any information on its medicines that would support the allegation of off-licence promotion.

The Panel noted that the complainant referred to the 7-10 slides in question being shown on the afternoon of 2 March. The Panel considered that whilst Janssen stated that the afternoon had not been live streamed its content still fell within the scope of the complaint.

The Panel noted that the afternoon session comprised a series of sessions and interactive case studies in breakout groups. The Panel noted that the slides referred to Janssen's products but noted Janssen's submission that none constituted off licence promotion. In particular, the Panel noted Janssen's submission that the reference to a

new generation anti-androgen, referred to in case study 2, was applicable to its product Erleada which was approved 4 weeks before the meeting.

The Panel noted that the complainant had not made clear which slides and statements were the subject matter of his/her concerns nor detailed why in his/her view such statements were in breach of the Code. It was not for the Panel to infer detailed reasons to support the allegation on behalf of the complainant. It was for the complainant to establish his/her case on the balance of probabilities. In the Panel's view, the complainant had not been sufficiently clear about the subject matter of the complaint and thus had not discharged his/her burden of proof to show that a breach of the Code had occurred and the Panel therefore ruled no breach of the Code.

The Panel noted that promotional material did not need to be labelled as such, however, it must not be disguised, and the identity of the responsible pharmaceutical company or a pharmaceutical company's involvement must be obvious at the outset.

The Panel noted that both the front and second page of the 'Save the Date' flyer, and the hard copy and online agenda stated that the meeting was initiated and funded by Janssen and that an independent faculty had determined the structure and scientific content of the meeting, albeit in small font in a footnote at the bottom of each page. The Panel noted that, in addition, both the front and second page of the 'Save the Date' flyer and the hard copy and online agenda included a Oncology Medical Education logo and a Janssen Oncology logo in the bottom left and right hand corners respectively. The flyer asked invitees to contact a Janssen medical manager for more information. The Panel also noted that the third slide of the 'Welcome and Introduction' presentation included a prominent Janssen Oncology logo and the previous slide included the declaration described above prominently displayed above the Janssen Oncology logo. The Panel noted Janssen's submission that delegates would expect the latest data to be discussed and as it was clearly a Janssen organised meeting it would be unreasonable to expect that Janssen products would not feature where appropriate in the context of educational talks. According to Janssen, where relevant, speakers included appropriate, accurate, balanced, objective and current information on Janssen and competitor products. In these circumstances and given Janssen's role in the meeting, its commercial interest, and the broad definition of promotion set out in the Code the Panel queried whether such a meeting could be considered as anything other than promotional. The Code required such meetings to include educational content.

The Panel noting its comments above and Janssen's involvement as set out at the outset on the 'Save the Date' flyer, agendas and the 'Welcome and Introduction' presentation did not consider that those invited would have expected anything other than a promotional meeting. The Panel queried whether information about Janssen's role should have appeared on all of the presentations however, on balance, considered that the promotional nature of the meeting was not disguised in the manner alleged by the complainant and ruled no breaches of the Code.

The Panel considered that the particular circumstances of this case did not warrant a ruling of a breach of Clause 2 of the Code which was a sign of particular censure and reserved for such use. No breach of Clause 2 was ruled.

An anonymous, non-contactable complainant who described themselves as a health professional complained about off-licence promotion which he/she alleged took place at a Janssen sponsored meeting, held on 1-2 March 2019 at the Park Plaza Riverbank Hotel, London. The meeting was entitled '8th Prostate Cancer Summit, Digital revolution: emerging evidence and technologies for tomorrow's clinical practice'.

Janssen marketed Zytiga (abiraterone) and Erleada (apalutamide) for use in the treatment of prostate cancer.

COMPLAINT

The complainant alleged that an external speaker who acted on behalf of Janssen, discussed 'off-licence' castrate resistant prostate cancer treatment on the afternoon of 2 March. The complainant considered that the information was misleading and indirectly promotional and was therefore not appropriate for the meeting at issue which was advertised as a medical educational event. The content contained at least 7-10 slides of unlicensed information which was disseminated to a wide UK audience as well as broadcast via a webinar. The complainant stated that he/she felt misled and let down by this event.

When writing to Janssen, the Authority asked it to consider the requirements of Clauses 2, 3.1, 3.2, 9.1 and 12.1 of the Code.

RESPONSE

Janssen explained that potential delegates were informed of the meeting via a 'Save the Date' flyer which directed them to a microsite to register their interest. The flyer made the following clear:

1 The meeting was initiated and funded by Janssen with Janssen Oncology branding also very visible.
2 An independent faculty led by the respected co-chairs had determined the structure and scientific content of the meeting.
3 The expectation of the meeting was to share cutting-edge knowledge and explore opinions from international and UK experts.

Delegates would expect the latest data to be discussed. As it was clearly a Janssen organised meeting it would be unreasonable to expect that Janssen products would not feature where appropriate in the context of educational talks. Where relevant, speakers included appropriate, accurate, balanced, objective and current information on Janssen and competitor products.

The agenda for this annual educational meeting was shaped by a steering committee of leading experts to reflect topics that were most relevant to UK clinical practice in prostate cancer. The learning objectives for the meeting were to:

- Draw from an exchange of ideas and techniques from experts from across the UK and beyond to enhance the diagnosis and management of prostate cancer.
- Ensure cutting edge clinical practice through acquisition of an update of relevant and recent scientific evidence.
- Incorporate use of digital technologies into clinical practice and prepare for the impact these would have on the roles of health professionals in the future.

The meeting was attended by approximately 275 health professionals (including faculty) as well as five who signed in for the pilot live stream component of the meeting.

Janssen noted the complainant's allegations about a presentation on the afternoon of 2 March included 7-10 slides of unlicensed information which was broadcast via a webinar.

In the absence of more specific information Janssen referred to the agenda for the live streamed component of the meeting and noted that:

1 Two sessions, in the morning between 09.40am and 11.45am, addressed castrate resistant prostate cancer (CRPC):
   a) Treatment decisions for CRPC
   b) Optimising treatment for patients with metastatic CRPC.

Janssen had reviewed the presentations in these sessions and could not identify any information on its medicines that would support the allegation of off-licence promotion. The licensed indication for the Janssen products mentioned in the CRPC sessions were as follows:

1 Zytiga (abiraterone) was indicated with prednisone or prednisolone for:
   - the treatment of newly diagnosed, high risk, metastatic, hormone sensitive prostate cancer (mHSPC) in adult men in combination with androgen deprivation therapy (ADT)
   - the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men who were asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy was not yet clinically indicated
   - the treatment of mCRPC in adult men whose disease had progressed on or after a docetaxel-based chemotherapy regimen.

   All Zytiga indications were approved before the meeting in question took place, the most recent was for mHSPC in November 2017.

2 Erleada (apalutamide):
   - Erleada was indicated in adult men for the treatment of non-metastatic castration resistant prostate cancer who were at high risk of developing metastatic disease.

   Erleada was approved on 28 January 2019.

Janssen gave details of each of the two CRPC sessions held on the morning of 2 March:

1 Treatment decisions for castrate resistant prostate cancer (CRPC)

This included a presentation titled 'Does non-metastatic CRPC exist, and should we treat it?' presented by three speakers. According to Janssen the first speaker set the scene with no reference to any Janssen product, the second presentation explored the role of novel radiographic imaging techniques with a single reference to Janssen product (slide 7) – abiraterone + prednisolone – which was in line with the licensed indication of abiraterone for metastatic CRPC as identified using the more advanced imaging technique under discussion,

and the third was a generic presentation of PSMA PET radiographic technique with no reference to any Janssen medicine.

This was followed by a presentation titled 'Keynote Presentation: The changing landscape of non-metastatic CRPC' which alongside competitor medicines referred to Janssen products all of which were within the licensed indication. Janssen submitted that the presentation was a fair and balanced review of the changing landscape of non-metastatic CRPC using data from 3 different trials of competing medicines without advocating any one medicine over another. No trade names or branding was used in line with the expectation of a scientific presentation and discussion.

Janssen listed the slides where its medicines were mentioned. In summary, two slides near the start of the presentation referred to registrational trials for Zytega in the mCRPC indication and a further nineteen slides referred to Erleada. Janssen submitted that it was possible that the complainant had overlooked the fact that Erleada was granted its first marketing authorization in the EU only 4 weeks before the meeting in question.

2 Optimising treatment for patients with metastatic CRPC

This session included a presentation titled 'New treatment options for metastatic CRPC'. Janssen noted, in particular, that a speaker spoke about the use of Radium- 223 in combination with Zytiga in patients with mCRPC. This was not a licensed combination and the speaker noted negative trial results which resulted in the EMA specifically amending the label for Radium-223 and contraindicating its combined use with Zytiga.

Based on the above, Janssen refuted any allegation that it had promoted any of its medicines either prior to the grant of a marketing authorization or outside of the terms of the licensed indications. Janssen denied breaching Clauses 3.1 and 3.2.

The only reference to an unlicensed combination of its medicine in CRPC was in the context of communicating a safety message to deter extended use in a population in which it was already approved, further demonstrating the high standards to which Janssen held itself. Janssen submitted that it had maintained high standards at all times and denied any breach of Clause 9.1.

The meeting was clearly a company paid for meeting of high educational value. Janssen acknowledged that balanced information on its products was appropriately referenced in the context of the clinical advances under discussion and denied any allegation of disguised promotion in breach of Clause 12.1. Given the above, Janssen did not consider that it had brought discredit to the industry and it thus denied a breach of Clause 2.

Janssen noted that its response was based on the limited information provided by the anonymous complainant who clearly stated that the slides in question were in relation to CRPC and that the content was disseminated more widely through a broadcast webinar. The only broadcast session that addressed CRPC as a topic was on the morning of Saturday 2 March. In response to the Panel's request for further information and clarification Janssen confirmed that none of the slides for the afternoon session were disseminated to the delegates who were present nor to those who had participated in the earlier broadcast webinar and/or a broader audience.

Janssen provided copies of the afternoon session slides and a summary of what each session covered. Breakout sessions took place between 13.30 and 15.40 and included sessions on Maintaining Quality of Life for Survivors of Prostate Cancer: Mental Health; Prostate cancer and Mental Health: An Overview; PATIENT 2.0: Care in the Information Age; Metabolic and endocrine perspectives; and Cardiovascular perspectives. Janssen submitted that none of these breakout sessions included reference to CRPC products. Interactive case histories were presented between 15.45 and 16.30 and included 3 case studies presented and chaired by Professors Clarke and Payne. The discussants included medical and clinical oncologists, a radiologist and a nurse consultant to reflect the treatment deliberations of a cancer MDT.

Case Study 1 described the clinical presentation of a patient with high risk metastatic hormone-sensitive prostate cancer (HRmHSPC). Including Abiraterone (Zytiga) as a treatment option for consideration was entirely appropriate and within its approved indication.

Case Study 2 described the clinical presentation of a patient with non-metastatic castrate-resistant prostate cancer(nmCRPC). Whilst there was no specific reference to a Janssen treatment as an option, the reference to 'a new generation anti-androgen' on slide 14 was applicable to Erleada (Apalutamide). Apalutamide was only approved 4 weeks prior to this meeting for the indication described by this patient's history. Janssen therefore denied that this constituted off label promotion.

Case study 3 described a patient with metastatic castrate-resistant prostate cancer (mCRPC). This was a patient whose cancer was progressing despite being on antiandrogen therapy. Slide 19 provided Janssen's Abiraterone (Zytiga) as an option for discussion. This was entirely appropriate and within its licensed indication.

Slide 20 asked the meeting Panel to consider if their treatment choice at this stage (mCRPC) might change if the patient had received a treatment with either docetaxel or abiraterone at the time of initial diagnosis with prostate cancer i.e. in a similar clinical setting to the patient in Case Study 1 and within the marketing authorisation for Abiraterone.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure stated that anonymous complaints would be accepted, but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant could not be contacted for further information.

The Panel noted that the complainant referred to a speaker who was acting on behalf of Janssen who had discussed 'off-license' castrate resistant prostate cancer treatment on the afternoon of 2 March 2019 which in his/her view was indirectly promotional, misleading and not appropriate for a meeting advertised as a medical educational event.

The Panel noted Janssen's submission that in the absence of more specific information it referred to the agenda for the live streamed component of the meeting and noted that two sessions, in the morning between 09.40am and 11.45am, addressed castrate resistant prostate cancer (CRPC): Treatment decisions for CRPC; and Optimising treatment for patients with metastatic CRPC. Janssen had reviewed the presentations in these sessions and could not

identify any information on its medicines that would support the allegation of off-licence promotion.

The Panel noted that the complainant referred to the 7-10 slides in question being shown on the afternoon of 2 March. The Panel considered that whilst Janssen stated that the afternoon had not been live streamed its content still fell within the scope of the complaint.

The Panel noted that the afternoon session comprised a series of sessions and interactive case studies in breakout groups. The Panel noted that the slides referred to Janssen's products but noted Janssen's submission that none constituted off licence promotion. In particular, the Panel noted Janssen's submission that the reference to a new generation anti-androgen, referred to in case study 2, was applicable to its product Erleada which was approved 4 weeks before the meeting.

The Panel noted that a morning presentation about Radium-223 therapy mentioned its use in combination with Zytiga and prednisone in a certain patient population which led to an increased risk of fractures and death, and which ultimately led to a Radium-223 label update for EMA countries contraindicating such use. On the information before it the Panel did not consider that the references to abiraterone in that presentation were in isolation promotional.

The Panel noted that the complainant had not made clear which slides and statements were the subject matter of his/her concerns nor detailed why in his/her view such statements were in breach of the Code. It was not for the Panel to infer detailed reasons to support the allegation on behalf of the complainant. It was for the complainant to establish his/her case on the balance of probabilities. In the Panel's view, the complainant had not been sufficiently clear about the subject matter of the complaint and thus had not discharged his/her burden of proof to show that a breach of Clauses 3.1 or 3.2 had occurred. The Panel therefore ruled no breach of Clauses 3.1 and 3.2.

The Panel noted that promotional material did not need to be labelled as such, however, it must not be disguised, and the identity of the responsible pharmaceutical company or a pharmaceutical company's involvement must be obvious at the outset.

The Panel noted that both the front and second page of the 'Save the Date' flyer, and the hard copy and online agenda stated that the meeting was initiated and funded by Janssen and that an independent faculty had determined the structure and scientific content of the meeting, albeit in small font in a footnote at the bottom of each page. The Panel noted that, in addition, both the front and second page of the 'Save the Date' flyer and the hard copy and online agenda included a Oncology Medical Education logo and a Janssen Oncology logo in the bottom left and right hand corners respectively. The flyer asked invitees to contact a Janssen medical manager for more information. The Panel also noted that the third slide of the 'Welcome and Introduction' presentation included a prominent Janssen Oncology logo and the previous slide included the declaration described above prominently displayed above the Janssen oncology logo. The Panel noted Janssen's submission that delegates would expect the latest data to be discussed and as it was clearly a Janssen organised meeting it would be unreasonable to expect that Janssen products would not feature where appropriate in the context of educational talks. According to Janssen, where relevant, speakers included appropriate, accurate, balanced, objective and current information on Janssen and competitor products. In these circumstances and given Janssen's role in the meeting, its commercial interest, and the broad definition of promotion set out in Clause 1.2 of the Code the Panel queried whether such a

meeting could be considered as anything other than promotional. The Code required such meetings to include educational content.

The Panel noting its comments above and Janssen's involvement as set out at the outset on the 'Save the Date' flyer, agendas and the 'Welcome and Introduction' presentation did not consider that those invited would have expected anything other than a promotional meeting. The Panel queried whether information about Janssen's role should have appeared on all of the presentations however, on balance, considered that the promotional nature of the meeting was not disguised in the manner alleged by the complainant and ruled no breach of Clause 12.1 and consequently no breach of Clause 9.1.

The Panel considered that the particular circumstances of this case did not warrant a ruling of a breach of Clause 2 of the Code which was a sign of particular censure and reserved for such use. No breach of Clause 2 was ruled.

Complaint received **20 June 2019**

Case completed **10 June 2020**