# ANONYMOUS, NON CONTACTABLE v JANSSEN

## Conduct of medical science liaison employee

**An anonymous, non-contactable complainant complained about the way in which one of Janssen's medical science liaison (MSL) team had offered information about the CANagliflozin cardioVascular Assessment Study (CANVAS) to a health professional at a primary care conference held in the UK. Canagliflozin (marketed by Janssen as Invokana) was indicated to improve glycaemic control in type 2 diabetes in adults.**

**The complainant stated that he/she saw the Janssen employee introduce him/herself to the health professional and ask him how he wished to receive information on the CANVAS study. When the health professional replied that he was uncertain about how to get such information, the MSL gave him a form to sign so the information could be delivered to him when the results were announced. According to the complainant this left the health professional, who would not complain personally, uncomfortable.**

**The detailed response from Janssen is given below.**

**The Panel noted that the parties' accounts about the exchange which had taken place differed; it was extremely difficult to know exactly what had transpired. It appeared that the complainant, who was non-contactable and so could not be asked for further information, had been an onlooker. The complainant bore the burden of proof on the balance of probabilities. A judgement had to be made on the available evidence. The complainant had provided very few details and no evidence to support his/her allegations. Conversely, Janssen had provided an email from the health professional in which he stated that he had no issue with the approach made to him by the Janssen MSL. This was inconsistent with the complainant's submission.**

**The Panel noted Janssen's submission that the health professional was one of the presenters at the meeting and that his presentation had included some data about the CANVAS study which was incorrect. In that regard the Panel considered that it was not unreasonable for the MSL to subsequently talk to him and draw attention to his error. The Panel noted that, provided that certain conditions were met, the Code excluded from the definition of promotion replies made in response to individual enquiries from health professionals or in response to specific communications from them whether of enquiry or comment, including letters published in professional journals. In the Panel's view, the MSL's response to inaccurate data being presented about the CANVAS study could take the benefit of that exemption provided that it was not inaccurate, misleading or promotional. Janssen submitted that as a result of his exchange with the MSL, the health professional asked to be kept updated on the emerging clinical data from the CANVAS study. Given the circumstances in which the exchange had arisen, the Panel did not consider that the MSL's reference to the CANVAS study, which had prompted the health professional to ask to be kept updated on the emerging clinical data, was such as to promote Invokana. No breaches of the Code were ruled including of Clause 2.**

An anonymous, non-contactable complainant complained about the way in which one of Janssen's medical science liaison (MSL) team had offered clinical trial information to a heath professional at the 12th National Conference of the Primary Care Diabetes Society (PCDS), held in Birmingham on 24/25 November 2016. The clinical trial at issue was the the CANagliflozin cardioVascular Assessment Study (CANVAS). Canagliflozin (marketed by Janssen as Invokana) was a sodium glucose co-transporter 2 (SGLT2) inhibitor indicated to improve glycaemic control in type 2 diabetes in adults.

### COMPLAINT

The complainant who did not wish to be contacted further, stated that he/she witnessed a member of the Janssen MSL team introduce him/herself to a health professional, and ask him how he wished to receive information on the CANVAS study. The MSL clearly did not know the health professional as he/she introduced him/herself stating they had not met before.

When the answer back was uncertain about how he would source such information, the MSL asked the health professional to sign a medical information form so the information could be delivered to him when the results were announced. According to the complainant this left the health professional uncomfortable. The health professional would not complain personally, but the complainant stated that he/she felt duty bound to highlight his dissatisfaction about the conduct of a member of the pharmaceutical industry.

When writing to Janssen, the Authority asked it to bear in mind the requirements of Clauses 2, 3.1, 3.2 and 9.1 of the Code.

### RESPONSE

Janssen submitted that CANVAS was an ongoing cardiovascular outcomes trial for canagliflozin studying people with type 2 diabetes who were at high risk of cardiovascular events, and were within the CANVAS programme. The integrated analysis of the CANVAS programme would enable Janssen to meet the US Food and Drug Administration (FDA) post-marketing requirement to study the cardiovascular safety of canagliflozin, as well as evaluate the impact for cardiovascular outcome with canagliflozin in type 2 diabetics. The CANVAS programme was near completion and expected

to report in 2017. No outcome data were currently available. There was significant interest in the clinical community on cardiovascular outcome studies on SGLT2 inhibitors.

Janssen submitted that the PCDS represented all health professionals involved with primary care diabetes, including GPs, practice nurses, GPs with a special interest and clinical assistants. The Janssen MSL attended the 2016 conference to represent Janssen, to fulfil his/her educational needs, build networks with health professionals and key opinion leaders and respond to scientific questions or concerns about canagliflozin raised by health professionals.

The incident raised by the complainant occurred following a presentation given by the heath professional, organised by the PCDS; Janssen was not involved in the organisation of the presentation. The health professional presented a timeline slide where the information on CANVAS was incorrect. The MSL approached the health professional at the end of the session, after conference delegates completed their discussions with him to ensure their conversation was private, to introduce him/herself as the MSL responsible for his region and to politely draw his attention to the error in the presentation. The discussion took place in the meeting room, not at the company stand.

The health professional stated that he would like to be kept updated on emerging clinical data from the CANVAS programme during the discussion. Hence, the MSL asked him to complete the Emerging Clinical Data Request Form, allowing the Janssen medical affairs team to provide updates in the context of scientific exchange according to the clinical interest as specified, provided it was in line with the Code. For the avoidance of doubt, this was in response to the health professional's request and was unsolicited.

The Janssen medical lead visited the health professional on 14 December 2016 to understand his recollection of the incident in question and also to determine whether there were any areas where the Janssen medical team could improve and if the health professional was uncomfortable with any part of the recent interaction, as alleged by the complainant. The health professional confirmed that his request for further information on CANVAS was unsolicited and furthermore, in writing, refuted the complainant's accusation that the Janssen MSL left him uncomfortable and dissatisfied about the conduct of a member of pharmaceutical industry. The health professional confirmed 'I personally have no issue at all with the approach made to me by the Janssen representative at the PCDS conference on 24 November 2016'. A copy of his statement was provided.

Janssen submitted that no material was sent to the health professional as he did not request materials on CANVAS. There were no specific UK instructions to MSLs about the use of the CANVAS study because currently there was no data available. There was no MSL briefing document specific to the PCDS national conference 2016. There were no CANVAS related materials at the promotional stand. Over 2 days of the PCDS meeting with approximately 700 delegates in attendance, Janssen received 4 reactive Emerging Clinical Data Requests on the CANVAS programme as follows:

One from the health professional in question as discussed above.

A speaker who asked the Janssen MSL about the CANVAS programme results and requested an update when results were available.

A delegate enquired about recent adverse events related to the CANVAS study which was communicated recently with a Dear Healthcare Professional Letter, as well as cardiovascular data currently available with canagliflozin. After being informed there was no cardiovascular data on CANVAS available, the delegate asked to be informed when the data was available.

A delegate who met the MSL the previous week (16 November) and requested an update on CANVAS, had been unable to complete the form at that time due to time restraints, and so agreed to meet at the PCDS to complete the request form.

Janssen stated that it took the Code extremely seriously, it was paramount for Janssen to build a trusted and collaborative relationship with health professionals. The Janssen MSL responded to an unsolicited request from a health professional to be kept updated on clinical development, in the context of scientific exchange according to the clinical interest specified by the health professional. There was no evidence to suggest the Janssen MSL promoted the use of canagliflozin outside of its marketing authorization, nor proactively promoted results of a clinical study which was yet to be reported and hence Janssen refuted breaches of Clauses 3.1 and 3.2. The company submitted that it had demonstrated that the Janssen MSL maintained a high standard and therefore there was no breach of Clause 9.1. The basis of this complaint was unfounded and Janssen submitted that it had not brought the pharmaceutical industry into disrepute, there was no breach of Clause 2.

**PANEL RULING**

The Panel noted that there were differences between the parties' accounts about the exchange which had taken place between the MSL and the health professional; it was extremely difficult in such cases to know exactly what had transpired. It appeared that the complainant, who was non-contactable and so could not be asked for further information, had been an onlooker. The complainant bore the burden of proof on the balance of probabilities. A judgement had to be made on the available evidence. The complainant had provided very few details and no evidence to support his/her allegations. Conversely, Janssen had provided an email from the health professional concerned in which he stated that he had no issue with the approach made to him by the Janssen MSL. This was inconsistent with the complainant's statement that the health professional was uncomfortable.

The Panel noted Janssen's submission that the health professional was one of the presenters at the meeting and had included some timeline data about the CANVAS study which was incorrect. In that regard the Panel considered that it was not unreasonable for the MSL to subsequently talk to the health professional and draw attention to his error. The Panel noted that Clause 1.2 of the Code excluded from the definition of promotion replies made in response to individual enquiries from health professionals or in response to specific communications from them whether of enquiry or comment, including letters published in professional journals, but only if they related solely to the subject matter of the letter or enquiry, were accurate and did not mislead and were not promotional in nature. In the Panel's view, the MSL's response to inaccurate data being presented about the CANVAS study could take the benefit of that exemption provided that it was not inaccurate, misleading or promotional. The Panel noted Janssen's submission that the health professional confirmed verbally at a meeting with its medical lead that his request for further information on CANVAS was unsolicited; this was not confirmed in his subsequent email. Janssen submitted that as a result of his exchange with the MSL, the health professional asked to be kept updated on the emerging clinical data from the CANVAS study. Given the circumstances in which the exchange had arisen, the Panel did not consider that the MSL's reference to the CANVAS study, which had prompted the health professional to ask to be kept updated on the emerging clinical data, was such as to promote Invokana. No breach of Clauses 3.1 and 3.2 were ruled.

The Panel noted its comments and rulings above and considered that there was no evidence that the MSL had not maintained high standards. No breach of Clause 9.1 was ruled.

Given its rulings above, the Panel ruled no breach of Clause 2.

During its consideration of this case, the Panel was concerned to note that Janssen appeared to use Emerging Clinical Data Request Forms to allow it to send updates to health professionals *ad infinitum* off the back of one request. The Panel queried whether, following the first provision of data, each subsequent sending of information could benefit from the exemption to promotion for replies made in response to individual enquiries given in Clause 1.2 of the Code. In addition, the Panel queried Janssen's submission that its medical affairs team provided such updates in the context of scientific exchange. In the Panel's view, the data flow was all one way, from Janssen to health professionals. The Panel considered that Janssen would be well advised to review its arrangements for the provision of clinical updates to ensure that they complied with the Code.

**Complaint received** **5 December 2016**

**Case completed** **10 January 2017**