CASE AUTH/2970/8/17

ANONYMOUS NON-CONTACTABLE v JANSSEN

Promotional email

An anonymous, non-contactable complainant submitted a complaint about the activities of a Janssen regional business manager (RBM). The complaint concerned the promotion of Invokana (canagliflozin) a sodium-glucose co-transport-2 (SGLT2) inhibitor. Invokana was indicated for the treatment of type 2 diabetes.

The complainant provided a copy of an email dated 22 June 2017 from the RBM to a GP which referred to a meeting the previous day.

Janssen explained that the GP also had a role for a GP federation, which represented a number of surgeries, including dispensing practices. Within this role, the GP led a review of dispensing deals across the federation.

The RBM had drafted a communication for the GP to comment on and ultimately send as well as a potential communication from a third party providing services for Janssen that Janssen was planning to send to the practices within the federation. The communication drafted for the GP to send referred to all SGLT2 inhibitors being recommended locally and that the federation had a preferred one, canagliflozin. As such, a preferential rate had been secured for the federated dispensing practices. A contact for clinical questions was included. This proposed communication stated that the third party service provider would be in touch to discuss the discount, relevant terms and conditions and the update of existing contracts and that as part of the diabetes programme Janssen had agreed a training programme to upskill diabetes knowledge and prescribing confidence in newer diabetes medicines. The proposed email from the third party service provider to individual practices referred to the communication from the named GP and the new [figure given] rebate for 'your practice'. It stated that this increased rebate was a result of the federation's decision to make Invokana the preferred SGLT2 product but was still in line with local guidance.

The RBM asked the GP whether the communication from the third party service provider could include the federation's logo. A table was to be included which listed each practice's current Invokana rebate which varied.

The complainant believed that the GP complained to Janssen about the email but was not sure it was being dealt with appropriately by Janssen. The complainant was also unsure that measures were being put in place in terms of training to stop the RBM sending such emails in the future.

The complainant was concerned that the wording in the email suggested that canagliflozin was the SGLT2 inhibitor preferred by the local prescribing and clinical effectiveness forum. This was inaccurate as it was jointly recommended within the class. There was also a suggestion of adding the federation logo to the third party's email communication to these surgeries in an attempt to add weight to the company's communications. The complainant queried whether a pharmaceutical company should try to influence the NHS in such a way. There was also a potential confidentiality breach given the sharing of the current discounts received by the GP surgeries without consent.

The detailed response from Janssen is given below.

The Panel noted that the email in question had been sent to the GP in his role for the local federation and purported to reflect an agreement reached at a meeting held with the RBM in question about Janssen's rebate scheme for dispensing practices. The email sought the GP's comments on a draft communication from the GP to the federation practices about an agreed preferential rate for canagliflozin. The second part of the email referred to a proposed communication from the third party service provider to relevant practices and the RBM asked whether the latter communication could have the federation logo on and stated that it would include the individual practice agreed discounts which were listed in the email.

The Panel had no way of knowing precisely what was said at the meeting between the RBM and the GP and therefore whether this was accurately reflected in the email. It appeared that the GP had not responded to the RBM's email but had contacted Janssen. The Panel noted the company's submission that the purpose of the email in question was to seek alignment and agreement for the wording of the wider communication. The Panel also noted the company's submission that the GP had confirmed to Janssen that he/she had requested a clarification email be sent so that he/she could understand the deal sufficiently to be able to take it to the federation for review. The Panel noted that there was an important difference between providing draft text for a communication to federation members and an email clarifying the agreement reached. The Panel queried whether this was the source of the GP's concerns. The Panel also noted that Janssen later stated a different rationale for sending the email namely to confirm the details of a conversation prior to formalising and communicating a contractual relationship. The Panel noted that it could be argued that the email in question did not make this sufficiently clear and in providing draft text for external communications went beyond the stated rationale. The Panel also noted that any external communication to federation members would have been subject to the company's approval and certification process.

Whilst the Panel had concerns about the email in question, there was no implication that the complainant considered that the rebate scheme was offered in connection with the promotion of medicines contrary to the requirements for terms of trade and the relevant supplementary information or that it was otherwise an inducement. No breach of the Code was ruled.

The Panel noted the complainant's concern that the email in question suggested to several surgeries that canagliflozin was the named local clinical effectiveness and prescribing forums 'preferred' SGLT2i which was inaccurate as it was jointly recommended in the class. The Panel noted that the email had not been sent to 'several surgeries' as implied by the complainant. The Panel noted that the first part of the email which covered the text of a proposed communication to relevant practices within the federation stated 'As you are aware, all SGLT2is are recommended locally. We as a federation have a preferred one within the class with canagliflozin'. The second proposed communication from the third party service provider stated that the 'increased rebate is as a result of the Federation's decision to make Invokana the preferred SGLT2 product but still in line with local guidelines'. In the Panel's view the first part of the email made it sufficiently clear that that all SGLT2is were recommended locally. However, the Panel considered that the second part of the email could have been clearer about the position of canagliflozin within the local guidelines. The Panel noted Janssen's submission that the wording of the email was less than ideal. Nonetheless, the Panel noted that whilst the email described Invokana as the federation's preferred SGLT2i, neither part of the email described it as the named local clinical effectiveness and prescribing forums 'preferred' SGLT2i as alleged. The Panel therefore ruled no breach of the Code based on the very narrow allegation.

The Panel noted that it might not necessarily be unacceptable to use the federation's logo on a communication to the individual practices within the federation provided that it was done with prior permission and appropriate approval and otherwise complied with the Code. The email made it clear that the addition of the logo was raised as a question, and, in the Panel's view, it was therefore for the federation to give its consent or otherwise. No communication had been sent to practices within the federation and the issue of disguised promotional activity did not arise. No breach of the Code was ruled in that regard.

The Panel noted that the complainant's allegation concerned what measures were now being put in place to ensure that the RBM was trained on relevant matters henceforth. On the limited information before the Panel it appeared that the training issues were now being addressed and no breach of the Code was ruled based on the narrow allegation.

The Panel considered that it was not unreasonable for the RBM to assume that the GP would be aware of the deals in place at the individual practices. The Panel considered that the RBM had been let down by the company in this regard. Nonetheless, confidential information had been disclosed by the RBM. This was a serious matter. The RBM had not maintained a high standard of ethical conduct and a breach of the Code was ruled. The Panel considered that the failure of Janssen to train the RBM before he/she discussed issues around confidential data with health professionals and on how to handle such data in accordance with the Code was a significant omission. High standards had not been maintained. A breach was ruled.

The Panel noted the complainant alleged that Janssen was not dealing with the GPs complaint appropriately. The Panel noted that the GP had not responded to Janssen's communications in July 2017. The complainant had not established that the GPs concerns were not being considered appropriately by Janssen and no breach was ruled in this regard.

The Panel noted its comments and rulings above. Noting that the proposed communications set out in the email did not advance past the draft stage, the Panel did not consider that a ruling of a breach of Clause 2 was warranted.

An anonymous, non-contactable complainant submitted a complaint about the activities of a Janssen regional business manager (RBM). The complaint concerned the promotion of Invokana (canagliflozin) a sodium-glucose co-transport-2 (SGLT2) inhibitor. Invokana was indicated for the treatment of type 2 diabetes.

The complainant provided a copy of an email dated 22 June 2017 from the RBM, to a GP which referred to a meeting the previous day.

Janssen explained that the GP had a role for the local GP federation which represented a number of surgeries, including a number of dispensing practices. Within his federation role, the GP led a review of dispensing deals across the federation.

The RBM had drafted a communication for the GP to comment on and ultimately send as well as a potential communication from a third party providing services to Janssen that Janssen was planning to send to the practices within the federation. The communication drafted for the GP to send referred to all SGLT2 inhibitors being recommended locally and that the federation had a preferred one, canagliflozin. As such, a preferential rate had been secured for the federated dispensing practices. A contact for clinical questions was also included. This proposed communication stated that the third party service provider, which managed Janssen's dispensing contracts, would be in touch to discuss the discount, relevant terms and conditions and the update of existing contracts. As part of the diabetes programme Janssen had agreed a training programme to upskill diabetes knowledge and prescribing confidence in newer diabetes medicines. The proposed email from the third party service provider to individual practices referred to

the communication from the named GP and the new 25% rebate for 'your practice'. It stated that this increased rebate was a result of the federation's decision to make Invokana the preferred SGLT2 product but was still in line with local guidance.

The RBM asked the GP whether the communication from the third party service provider could include the federation's logo. A table was to be included which listed each practice's current Invokana rebate which varied. The proposed communication would include contact details for clinical questions and the training programme.

COMPLAINT

The complainant stated that he/she had been made aware of an email sent by a Janssen RBM to a named GP regarding discounted pricing which the complainant alleged was in breach of the Code.

The complainant believed that the GP complained to Janssen about the email but was not sure it was being dealt with appropriately by Janssen. The complainant was also unsure that measures were being put in place in terms of training to stop the individual concerned sending such emails in the future.

The complainant was concerned that the wording in the email suggested to several surgeries that canagliflozin was the SGLT2 inhibitor preferred by the local prescribing and clinical effectiveness forum. This was inaccurate as it was jointly recommended within the class.

There was also a suggestion of adding the federation logo to a third party's email communication to these surgeries in an attempt to add weight to the company's communications. The complainant queried whether a pharmaceutical company should try to influence the NHS in such a way. There was also a potential confidentiality breach. Confidential information had been shared of the current discounts received by the GP surgeries without the consent of the surgeries concerned or the third party service providers.

In writing to Janssen, the Authority asked it to bear in mind the requirements of Clauses 7.2, 7.4, 9.1, 12.1, 15.2, 16.1, 18.1 and 2 of the Code.

RESPONSE

Janssen acknowledged a breach of Clauses 9.1 and 15.2 of the Code. It denied any breach of the Code regarding Clauses 7.2, 7.4, 12.1, 16.1, 18.1 or 2.

Janssen confirmed it had received an email from the GP at issue on 3 July. Janssen submitted that this was being addressed prior to the arrival of the anonymous complaint sent to PMCPA on 8 August. The points raised by the GP in the email dated 3 July concerned different (albeit related) aspects of the email sent to him from the RBM on 22 June.

Janssen explained that it operated a simple rebate scheme, the manufacturing discount scheme (MDS), for dispensing doctors whereby organisational purchases above a certain volume qualified for an annual rebate back to the organisation. This was a standard purchasing deal with a healthcare organisation that did not construe a benefit to any individual. This type of arrangement with hospitals, retail pharmacies and dispensaries in GP practices had been in place across the industry for many decades (certainly since before 1993) and therefore fell outside the scope of the Code as defined by the supplementary information to Clause 18.1. Accordingly, Janssen denied breaches of Clause 18.1.

The GP in question (in his/her role for the local federation) met with the RBM in question and an account manager on 21 June to discuss the MDS for Invokana and the discounts that might be available for members of the federation. The intention was to negotiate a group discount, whereby the collective of dispensaries (within the federation) might secure a higher discount than might be achievable individually through higher overall future volume purchases.

Following the meeting the RBM wrote to the GP (22 June) to confirm their mutual understanding of the arrangements so that the offer could be made to the wider group. The GP had subsequently confirmed that he/she requested the clarification email be sent to ensure he/she understood the deal sufficiently to be able to take it to the federation for review. Unfortunately, the GP was concerned about the email specifically with regard to its content and tone, as it did not accurately reflect his/her understanding of the conversation and breached confidentiality.

Within the email, the RBM suggested, based on his/her understanding from the meeting, specific content that the GP might use to write to the federation members; and also content that the third party service provider might use as part of a co-ordinated communication. As per Janssen policy, the final communications would have been reviewed and certified by Janssen and distributed with prescribing information, etc, as a formal promotional communication. This intent was indicated in the opening paragraph:

> 'As promised, here is the communication for you to have a look at and also our potential communication we are planning to send the practices from ….'

On 3 July, the GP emailed Janssen to express his/her concerns regarding the RBM's email.

Janssen understood that the GP's primary concerns about the email were in relation to the accuracy of the comments attributed to him/her by the RBM and the confidentiality of the commercial information shared. Janssen believed that these concerns stemmed from a genuine misunderstanding by the RBM and as such had already apologised to the GP.

Janssen acknowledged that the RBM's email could have been written differently, the clear and indisputable purpose was to seek the GP's alignment and agreement for the wording of the

wider communication. In that context there was no intention to mislead; indeed the exact opposite was true. In case the two parties had a different interpretation of the commercial discussion, the GP was given the opportunity to correct any inconsistencies. Accordingly, Janssen concluded that the rationale for sending the email - confirming the details of a conversation prior to formalizing and communicating a contractual relationship – was appropriate; even though the specific content was less than ideal.

Janssen addressed the specific concerns.

Allegation: 'The email implies that Canagliflozin was the SGLT2i inhibitor preferred by the local prescribing and clinical effectiveness forum'

For clarity, the local prescribing and clinical effectiveness forum was a strategic advisory network with the responsibility of ensuring the cost-effective use of medicines and other healthcare interventions and their functional integration into local healthcare delivery. The local formulary guidance was available online for SGLT2 inhibitors.

Specifically the 22 June email from the RBM to the GP stated:

> 'As promised, here is the communication for you to have a look at and also our potential communication we are planning to send the practices from ….
>
> As you are aware, all SGLT2is are recommended locally. We as a federation have a preferred one within the class with canagliflozin. As such, we have secured a preferential rate for all our federated dispensing practices.'

Janssen stated that it would have been helpful if the second paragraph was presented in italics to clearly indicate this was the proposed text for the communication to the wider federation members. However, a considered reading of the email layout and structure did make this apparent.

Later in the email, attention turned to the potential for the deal to also be communicated by the third party service provider. Again, the GP was asked to comment on the proposed text for use by the agency. Again, there was no inference that the local prescribing and effectiveness forum preferred canagliflozin – in fact the use of the word 'but' made it clear that the preferential positioning of canagliflozin by the GP federation (as was understood by the RBM when he/she wrote the email) was different from the approach taken by the local prescribing and effectiveness forum.

> 'Following [the GP's] communication to you regarding Invokana we are calling on behalf of Janssen to set you up on a new 25% rebate for your practice. This increased rebate is as a result of the Federation's decision to make Invokana the preferred SGLT2 product but still in line with local guidance from the local prescribing and effectiveness forum.'

It was clear that nothing in the email claimed or purported to imply that canagliflozin was preferred by the local prescribing and effectiveness forum and was intended to check the understanding of the position of the federation prior to any formal, approved communication. Accordingly, Janssen denied breaches of Clauses 7.2 and 7.4.

For clarity, the third party service provider was a commercial service. It was a J&J and MHRA approved company which offered a specialist service for communicating commercial discounts (non-clinical activity) with dispensing practices. The third party service provider delivered a number of activities for Janssen including setting up MDS (manufacturer discount schemes) with agreed accounts to receive discounts via rebate through their nominated wholesaler based on purchases in line with the Janssen dispensing scheme and administering the Janssen dispensing account contracts.

Allegation: Disguised promotion

Janssen submitted that the specific reason for listing Clause 12.1 was not clear as this did not appear to be an allegation of the complaint. Janssen assumed this was either in relation to the email to the GP, or in relation to the potential communication from the GP to the federation members.

Since the purpose of the 22 June email to the GP was to check and clarify the agreement reached in their meeting, as requested by the GP, and to suggest the content of a proposed subsequent communication, Janssen did not regard the email to the GP as disguised promotion and accordingly denied breaches of Clause 12.1. Additionally, the heading and content of the email were clearly about 'dispensing' and clearly sought the GP's views on the proposed group communication; the content and intention of the RBM's email was not in any sense disguised promotion.

Allegation: The email implies that including the federation logo on a communication is inappropriate

The RBM sought permission to add the federation logo to the communication from the third party service provider. Janssen submitted it was not inappropriate to seek permission to use the federation logo in respect of a deal negotiated with its members in a communication to its members to indicate the federation's support for that deal. There was no suggestion that Janssen's involvement would be absent from the communication, which would have been approved and certified prior to dissemination according to Janssen policy.

Accordingly, Janssen denied any breach of Clause 12.1 regarding disguised promotion, especially since the form of the communication in question had not even been formally drafted, let alone submitted for approval or disseminated and was preliminary in nature, as the email indicated.

Allegation: The email implies that including the specific discounts of the surgeries in the federation was a confidentiality breach

Janssen stated this was one of the key points in the GP's email of 3 July to Janssen Diabetes.

Janssen noted that the RBM openly stated the discounts in place for each of the federation members in his/her email to the GP.

All Janssen employees, including the RBM were trained on a wide variety of policies as part of their business conduct training, including the need to respect data privacy principles.

Janssen had confidentiality agreements in place with each of the surgeries for whom a specific discount was listed. It would therefore be inappropriate for Janssen to share those discounts with other individual members of the federation. Further, while the RBM gave the impression that the whole table was to be included in the third party service provider communication, this had not been – and would never have been – approved during the certification of the formal communication; and no communication had actually occurred, other than to the official negotiator, the GP in question.

Further to its internal investigation Janssen confirmed that the RBM, mistakenly, believed he/she was negotiating with the GP on behalf of the federation and assumed that the GP, in his/her role for the federation, already knew the commercial arrangements in place with each practice. The GP had since confirmed that this assumption was incorrect. Accordingly, Janssen had apologised to the GP, and accepted it was not appropriate for him/her to see the individual practice discounts currently in place between those practices and Janssen.

Accordingly, Janssen acknowledged a breach of Clauses 9.1 and 15.2 because the RBM inappropriately shared commercially confidential information on behalf of Janssen with an unauthorised third party.

Allegation: That the GP's complaint was not being dealt with appropriately

Janssen stated that obviously, the PMCPA would understand that investigations into complaints were not something the company publicised internally or externally and therefore there was no reason for the anonymous complainant to be aware of either the complaint or any actions Janssen might have taken.

Janssen submitted that it operated to the highest possible standards and it took immediate action to investigate the GP's concerns.

Janssen submitted that the timetable of events and actions (details provided) clearly demonstrated that it had commenced internal investigations and referred the findings for human resources review before it received the communication from the PMCPA and within the timeframe agreed with the GP.

The complainant also alleged a lack of training had been 'put in place' to stop the individual concerned 'sending such emails in the future'. Should Janssen decide that specific training was necessary, it would be established in line with the company disciplinary procedures. Janssen stated that the PMCPA would understand why this would not be for public consumption and would not be brought to the attention of the anonymous complainant.

The RBM received regular Code training and was last trained in July 2016.

Accordingly, Janssen denied a breach of Clause 16.1.

Clause 2

While Janssen acknowledged that the content of the RBM's email to the GP resulted in the GP contacting the company, it acted rapidly to clarify the issues and to take positive steps to alleviate the concerns.

While the company acknowledged that the RBM's actions were not ideal, it did not believe that he/she acted with any malice or intention to mislead. No communications were sent to any health professional other than an appointed negotiator for a purchasing group. The email to the GP was sent with the specific intention of clarifying the details of the deal and seeking agreement on the text and nature of the communication of that deal to the purchasing group he was representing.

Accordingly, Janssen submitted that its actions or those of its employees did not bring the industry into disrepute and consequently denied any breach of Clause 2.

Janssen submitted that it had email permission from the GP recorded in its system.

Janssen submitted that both the account manager who had accompanied the RBM and the RBM had passed the ABPI Representatives Examination.

The training referred to in the email in question related to the standard, fully approved, meetings that Janssen account managers routinely offered. The exact format of the training 'programme' had not yet been formalized; an aspect that would have been confirmed and agreed prior to any formal communication.

Janssen confirmed that no representatives from Napp were either present at the meeting with the GP or were involved with the discussions. The reference to Napp was only in the context of the co-promotion agreement in place between Janssen and Napp for the promotion of Invokana. The GP was familiar with the co-promotion agreement and with the local Napp account manager, which was why they were mentioned in the email, however, Napp had no involvement in this particular discussion.

In conclusion, Janssen acknowledged a breach of Clause 9.1 and 15.2 of the Code but denied any breach of Clauses 2, 7.2, 7.4, 12.1, 16.1 or 18.1.

In response to a request for further information Janssen provided the complete training history for the RBM concerned. The company noted that he/she had been trained on 5 modules which all

Janssen employees completed as part of their core curriculum in relation to email and email communication and had additionally been trained on another two relevant modules specific to the RBM role.

Upon the resolution of this case Janssen would implement any additional training, pertaining to email, or otherwise, to address any gaps that were identified.

Janssen summarised the training history for the RBM in relation to emails and email communication and provided an outline of the relevant learning objectives (details provided). Janssen confirmed that all trainings were up-to-date and noted that in addition to these trainings the RBM concerned was also trained on the 2016 Code and had completed the ABPI Representatives Examination.

Janssen also summarised the training history for the RBM concerned related to business conduct and data privacy and provided an outline of the relevant learning objectives (details provided). Again Janssen confirmed that all training was up-to-date.

Janssen submitted that it currently did not train RBM's or account managers specifically on confidentiality agreements in place with dispensing surgeries. Janssen acknowledged that this was a gap. As such, Janssen confirmed that the RBM was not trained on the confidentiality agreements in place with the dispensing surgeries in question. After the resolution of this case Janssen stated that it would ensure that training on these would be incorporated into curriculum for relevant staff going forward.

Janssen reiterated that the RBM concerned only shared the information assuming that the GP, operating as director of finance for the local federation, already knew the commercial arrangements in place with each practice and as such it was an honest mistake.

Janssen noted that, as demonstrated by the numerous policies and trainings it had in place with regards to business conduct and privacy, despite identifying this specific gap, employees were comprehensively trained on the general principles of business conduct, privacy and email communication.

Janssen provided a copy of the local formulary with regard to the use of SGLT2 inhibitors.

The development of the formulary was overseen by the local prescribing and effectiveness forum working in conjunction with the drugs and therapeutics committee hence the reference in the case to the local prescribing and effectiveness forum formulary, however, these were one and the same.

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. The Panel noted that extreme dissatisfaction was usually required on the part of an individual before he or she was moved to complain. All complaints were judged on the evidence provided by the parties. The complainant could not be contacted for more information.

The Panel noted that the email in question had been sent to the GP in his role for the local federation and purported to reflect an agreement reached at a meeting with the RBM in question about Janssen's rebate scheme for dispensing practices within the federation. The email sought the GP's comments on a draft communication from the GP to relevant practices within the federation about an agreed preferential rate for canagliflozin. The relevant part of the email concluded with 'Let me know if this is ok?' The second part of the email referred to a proposed communication from the third party service provider to relevant practices within the federation and introduced the text stating 'we wanted to put something along the lines of:' The RBM asked whether the latter communication could have the federation logo on and stated that it would include the table of existing individual practice agreed discounts which was also reproduced in the email.

The Panel noted the status of the complainant above. The Panel had no way of knowing precisely what was said at the meeting between the RBM and the GP and therefore whether this was accurately reflected in the email. It was not possible to contact the complainant for further details. It appeared that the GP in question had not responded to the RBM's email but had contacted Janssen. The Panel noted the company's submission that the purpose of the email in question was to seek alignment and agreement for the wording of the wider communication. The Panel also noted the company's submission that the GP had confirmed to Janssen that he/she had requested a clarification email be sent to ensure that he understood the deal sufficiently to be able to take it to the federation for review. The Panel noted that there was an important difference between providing draft text for a communication to federation members and an email clarifying the agreement reached. The Panel queried whether this was the source of the GP's concerns. The Panel also noted that Janssen later stated a different rationale for sending the email namely to confirm the details of a conversation prior to formalising and communicating a contractual relationship. The Panel noted that it could be argued that the email in question did not make this sufficiently clear and in providing draft text for external communications went beyond the stated rationale. The Panel also noted that any external communication to federation members would have been subject to the company's approval and certification process. The Panel considered that sending an email to confirm the terms of an agreement reached during such meetings about terms of trade and to seek comment on proposed communications was, in general terms, good practice.

The Panel noted that the case preparation manager had raised and the company had responded to the requirements of Clause 18.1 and its supplementary information, Terms of Trade which stated that such measures or trade practices which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993 were excluded from the provisions of that clause. Whilst the Panel had concerns about the email in question, in its view the complainant did not raise a Clause 18.1 matter. There was no implication that the complainant considered that the rebate scheme was offered in connection with the promotion of medicines contrary to Clause 18.1 and the relevant supplementary information or that it was otherwise an inducement. No breach of Clause 18.1 was ruled.

The Panel noted the complainant's concern that the email in question suggested to several surgeries that canagliflozin was the [named local clinical effectiveness and prescribing forum] 'preferred' SGLT2i which was inaccurate as it was jointly recommended in the class. The Panel noted that the email had not been sent to 'several surgeries' as implied by the complainant. The Panel noted that the first part of the email which covered the text of a proposed communication to relevant practices within the federation stated 'As you are aware, all SGLT2is are recommended locally. We as a federation have a preferred one within the class with canagliflozin'. The second proposed communication from the third party service provider stated that the 'increased rebate is as a result of the Federation's decision to make Invokana the preferred SGLT2 product but still in line with local guidelines'. In the Panel's view the first part of the email made it sufficiently clear that that all SGLT2is were recommended locally. However, the Panel considered that the second part of the email could have been clearer about the position of canagliflozin within the local guidelines. The Panel noted Janssen's submission that the wording of the email was less than ideal. Nonetheless, the Panel noted that whilst the email described Invokana as the federation's preferred SGLT2i, neither part of the email described it as the [named local clinical effectiveness and prescribing forum] 'preferred' SGLT2i as alleged. The Panel therefore ruled no breach of Clauses 7.2 and 7.4 based on the very narrow allegation.

The complainant was concerned that the suggestion to add the federation logo to the communication from the third party service provider was an attempt by the company to add weight to the communication and influence the NHS. The Panel noted that Clause 12.1 stated that promotional material and activities must not be disguised. The Panel noted that it might not necessarily be unacceptable to use the federation's logo on a communication to the individual practices within the federation provided that it was done with prior permission and appropriate approval and otherwise complied with the Code. The Panel noted that the email in question made it clear that the addition of the logo was raised as a question, and in the Panel's view it was therefore for the federation to give its consent or otherwise. The Panel considered that it was not an unacceptable suggestion. In any event no communication had been sent to practices within the federation and the issue of disguised promotional activity did not arise. No breach of Clause 12.1 was ruled in that regard. The Panel noted that Clause 16.1 required that all relevant personnel including representatives and members of staff, and others retained by way of contract, concerned in any way with the preparation or approval of material or activities covered by the Code must be fully conversant with the Code and the relevant laws and regulations. The Panel noted Janssen's submission about its training program and that the individual had received regular Code training and was last trained in July 2016. The Panel noted Janssen's submission that it currently did not train RBM's or account managers specifically on confidentiality agreements in place with dispensing surgeries and acknowledged that this was a gap. The RBM in question had not been trained on the confidentiality agreements in place with the dispensing surgeries in question. The Panel further noted Janssen's submission that after the resolution of this case it would ensure that training on these would be incorporated into curriculum for relevant staff going forward and it would implement any additional training, pertaining to email, or otherwise, to address any gaps that were identified. The Panel noted that the complainant's allegation concerned what measures were now being put in place to ensure that the RBM was trained on relevant matters henceforth. On the limited information before the Panel it appeared that the training issues were now being addressed. The Panel therefore ruled no breach of Clause 16.1 based on the narrow allegation.

The Panel noted Janssen's explanation that the health professional at issue also had a role for the local federation, which represented a number of surgeries, including a number of dispensing practices. Within his/her federation role, the health professional led a review of dispensing deals across the federation.

Noting its comments above with regard to the RBM in question not being trained on the confidentiality agreements in place within the individual dispensing surgeries in question, the Panel considered that it was not unreasonable for the RBM to assume that the GP in his/her role as described above would be aware of the deals in place at the individual practices. The Panel considered that the RBM had been let down by the company in this regard. Nonetheless, the confidential information pertaining to a number of practices, excluding that of the GP, had been disclosed by the RBM. This was a serious matter. The Panel considered that disclosing such information did not comply with the requirements of the Code and a high standard of ethical conduct had not been adhered to as required by Clause 15.2 and a breach of that clause was ruled. The Panel considered that the failure of Janssen to train the RBM before he/she discussed issues around confidential data with health professionals and on how to handle such data in accordance with the Code was a significant omission. High standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel noted that the complainant had alleged that Janssen was not dealing with the GPs complaint appropriately. No further details were provided.

The Panel noted Janssen's submission on this point and that the GP had not responded to Janssen's communications in July 2017 to update him/her on the progress of its investigation. The complainant had not established that the GPs concerns were not being considered appropriately by Janssen and no breach of Clause 9.1 was ruled in this regard.

The Panel noted its comments and rulings above. Noting that the proposed communications set out in the email did not advance past the draft stage, the Panel did not consider that a ruling of a breach of Clause 2 was warranted in the particular circumstances of this case.

During its consideration of this case the Panel noted that the communication was a draft and had only been sent to the named health professional. It did not appear that the communication had been sent to any of the individual practices. However, the Panel queried the RBM's understanding of the Code if he/she considered such an arrangement to be appropriate under the Code.

The Panel requested that Janssen be advised of its concerns.

Complaint received **8 August 2017**

Case completed **1 February 2018**