Case AUTH/2732/9/14

VOLUNTARY ADMISSION BY JANSSEN

Invokana letter misleading for some GPs

Janssen voluntarily admitted that it had sent some GPs a misleading 'Dear Doctor' letter about its antidiabetic medicine, Invokana (canagliflozin).

In accordance with Paragraph 5.6 of the Constitution and Procedure the matter was treated as a complaint.

Janssen explained that the letter was sent to GPs in 150 clinical commissioning groups (CCGs). The letter stated that Invokana had been approved by the local formulary process and was available to be prescribed in accordance with guidance from the National Institute for Health and Care Excellence (NICE), however in 39 CCGs only consultant physicians could initiate Invokana therapy. Janssen submitted that for these CCGs it had thus not accurately portrayed the local situation and believed that it might have breached of the Code.

Janssen stated that following a complaint from a GP it realised the error and immediately put in place a corrective action plan to apologise for and correct the inaccuracy. Janssen stated that it took its responsiblities under the Code very seriously and regretted this unfortunate error and would implement steps to ensure it did not recur.

Further details from Janssen are given below.

The Panel noted that the letter, sent to the GPs, was headed 'Invokana (canagliflozin) available to prescribe in [named CCG]'. The letter began 'I am writing to inform you that following the NICE Technology Appraisal Guidance (TAG) for the use of Invokana (canagliflozin) in England and Wales, it has been approved by your local formulary process and is available to prescribe in [named CCG].' The Panel noted that for some recipients this was not so; the letter had been sent to some GPs where, although Invokana was on the CCG formulary, it was not available for them to prescribe. The Panel considered that the letter was misleading in this regard. A breach of the Code was ruled. The Panel further considered that the error was likely to have created confusion and additional work in some CCGs. The Panel considered that high standards had not been maintained and a breach of the Code was ruled.

Janssen voluntarily admitted that it had sent some GPs a misleading 'Dear Doctor' letter (ref PHGB/VOK/0714/0029a) about its antidiabetic medicine, Invokana (canagliflozin).

In accordance with Paragraph 5.6 of the Constitution and Procedure the matter was treated as a complaint.

VOLUNTARY ADMISSION

Janssen explained that the letter was emailed or sent by post on 16 September to GPs in 39 clinical commissioning groups (CCGs) in England. The letter stated that Invokana had been approved by the local formulary process and was available to be prescribed in accordance with guidance from the National Institute for Health and Care Excellence (NICE), however GPs in those particular CCGs did not necessarily have freedom to prescribe Invokana. Janssen submitted that it had thus not been accurate in its portrayal of the local situation and believed that it might have breached Clause 7.2.

The same letter was also posted or emailed on the same day to GPs in 111 CCGs where this prescribing freedom existed and in that regard Janssen believed these letters were accurate.

Janssen considered that as the breach was caused by human error, and not picked up by an existing company procedure, it had not maintained its usual high standards in relation to compliance with the Code and therefore it also believed that it might have breached Clause 9.1.

Copies of the letter and the email, as well as their certificates, were provided.

Janssen stated that following a complaint from a GP prescribing lead of a CCG it realised the error and immediately put in place a plan to contact all involved CCGs to apologise and offer remedial actions, including the sending of a further email or letter, after agreement of the relevant CCG, to correct the inaccuracy.

Janssen stated that it took its responsiblities under the Code very seriously and sincerely regretted this unfortunate error and would implement steps to ensure it did not recur.

Janssen was asked to comment on this matter in relation to Clauses 7.2 and 9.1 of the Code.

RESPONSE

Janssen explained that the letter was intended to let GPs know that Invokana was on formulary and available to prescribe in their CCGs. This information was what the CCG made availalbe to all prescribers within the CCG, as part of its requirement to implement NICE-approved medicines. NICE guidance for Invokana was published on the 25 June 2014.

CCGs indicated formulary approval via a tiered, generally colour coded system, whereby at one end of the spectrum a GP had full freedom

to initiate and prescribe and on the other end, although Invokana was available on formulary, only consultant physicians could initiate a prescription. Through interactions with local stakeholders, the Janssen health economy liaison managers (HELMs) ascertained when Invokana had been approved by the CCG on local formulary and confirmed this via the CCG website where applicable (ie if formulary was published or immediately updated). If the CCG had not yet posted its formulary status online, Janssen got confirmation from when specialists and/or GPs could prescribe and sought guidance on when it could communicate this to GPs via the Janssen account managers (AMs). After every formulary approval, the Janssen local account team, led by the HELM, completed a tracker to confirm the local formulary status, this was then checked by the regional business managers and regional market access managers. The tracker was stored and updated on an internal Janssen site.

An unfortunate internal oversight meant that the letter at issue, which was intended to be sent to CCGs that had full GP freedom to prescribe, was sent to all CCGs where Invokana was on the formulary (ie it was sent in 39 CCGs where there was not full GP freedom to prescribe).

Janssen stated that it briefed its HELMs and AMs by telephone on 17 September to tell them about the issue and agree actions for the HELMs in terms of making the CCG prescribing leads aware of the error. This verbal briefing was followed by a written interal briefing to the HELMs on 18 September and to the AMs on the 24 September.

As of 6 October, senior Janssen staff had contacted four CCGs that had complained directly to the company, to apologise and discuss potential remedial actions.

Janssen submitted that all of the 39 CCGs that did not necessarily have GP freedom to prescribe Invokana had received an apology from the HELM for their respective regions and Janssen had offered to send a retraction letter and email to all GPs in the 39 CCGs and if accepted, it would agree the content with the individual CCG before it was sent. If a CCG prescribing lead requested any specific amends to the standard letter or email, it would be amended and certified by Janssen before being sent.

PANEL RULING

The Panel noted that the letter, sent to the GPs, was headed 'Invokana (canagliflozin) available to prescribe in [named CCG]'. The letter began 'I am writing to inform you that following the NICE Technology Appraisal Guidance (TAG) for the use of Invokana (canagliflozin) in England and Wales, it has been approved by your local formulary process and is available to prescribe in [named CCG].' The Panel noted that for some recipients this was not so; the letter had been sent to some GPs where, although Invokana was on the CCG formulary, it was not available for them to prescribe. The Panel considered that the letter was misleading in this regard. A breach of Clause 7.2 was ruled. The Panel further considered that the error was likely to have created confusion and additional work in some CCGs. The Panel considered that high standards had not been maintained. A breach of Clause 9.1 was ruled.

Complaint received **18 September 2014**

Case Completed **20 October 2014**