

CASE AUTH/2611/6/13 NO BREACH OF THE CODE

ANONYMOUS RENAL NURSE v JANSSEN

Durogesic promotional aid

An anonymous, non-contactable, renal nurse complained that Durogesic DTrans (fentanyl trans-dermal patch) branded pens had been included in delegate bags at the British Royal Society (BRS) Meeting in Manchester, 14 to 16 May 2013. Durogesic was marketed by Janssen and was indicated in adults in the management of chronic intractable pain, whether due to cancer or otherwise, and in the long-term management of severe chronic pain in children receiving opioid therapy from 2 years of age.

The detailed response from Janssen is given below.

The Panel noted that in March 2010, an unspecified quantity of the branded pens had been donated to the BRS following a request for practical support from the industry. The Panel assumed that given their subsequent provision in delegate bags, Janssen must have donated a large number of pens and so it was not unreasonable to expect that the pens would be redistributed. The Panel noted Janssen's submission that there was no promotional intent in the supply of the pens to the BRS but considered that given the product logo, they could not be considered as anything other than promotional aids. When they were donated, branded pens were acceptable promotional aids under the 2008 Code. The Panel queried, however, whether the branded pens at issue should have been donated to the BRS at all given Janssen's submission that Durogesic DTrans was not routinely used in renal medicine. In that regard the Panel noted that the current summary of product characteristics recommended that if patients with renal impairment received Durogesic DTrans, they should be observed carefully for signs of fentanyl toxicity and the dose reduced if necessary. The Panel further noted that the 2011 Code (effective from 1 January, 2011 but with a transition period until 30 April, 2011) onwards prohibited the use of branded pens as promotional aids.

The Panel noted that branded pens, donated in 2010 by Janssen to the conference organisers, had been distributed in the delegate bags in 2013. The Panel noted Janssen's submission that it first knew about the provision of the pens on 16 May via another pharmaceutical company. The Panel noted that the conference brochure clearly stated that the pens had been donated by Janssen in 2010 and it queried how Janssen did not apparently see that statement and thus know about the provision of the pens before being alerted to the fact by a third party on the last day of the conference. The Panel noted that the provision of branded pens was no longer acceptable under the Code. A breach of the Code was ruled.

Upon appeal by Janssen the Appeal Board noted that approximately 5,000 pens displaying the Durogesic DTrans product logo had been donated to in 2010 after a request for practical support. Janssen envisaged that the pens would be used for BRS meetings including the annual conference in 2010 which according to BRS had approximately 1,500 attendees. The company assumed that the pens would be distributed over 2 years including the 2011 annual conference held in the spring. The Appeal Board noted the submission from the BRS that the pens would also have been distributed at smaller meetings. The Appeal Board noted that following the donation in 2010 there had been no further discussion between the parties about the pens. There were other sponsors for its 2011 and 2012 conferences. In the absence of a sponsor in 2013 it unilaterally decided to retrieve the pens from storage for use at its conference.

The Appeal Board noted that prior to the 2011 Code pens with brand names could be distributed to health professionals under that edition of the Code and it considered that the prohibition of such pens introduced in the 2011 Code was not retrospective. However, it did not necessarily agree with Janssen's statement that as the industry had not been required to withdraw items given to individual

health professionals the company could not have been expected to withdraw the pens given to an organisation such as the BRS.

The Appeal Board noted that the BRS conference brochure for 2013 stated that the pens had been donated by Janssen in 2010. The Appeal Board noted that the Janssen representative at the 2013 BRS conference had not seen the delegate pack. The Appeal Board was concerned that Janssen had not seen the conference brochure given it had a promotional stand at the conference. The Appeal Board noted that Durogesic was not routinely used in renal patients.

The Appeal Board considered that a large number of pens had been donated in 2010 and these needed to be used by the end of the transition period, ie 30 April 2011. The Appeal Board noted that whilst Janssen had donated the pens to BRS it was not thereby absolved of all responsibility under the Code in relation to their future use. Although it was concerned at the large number donated for redistribution, it considered that given the number of attendees at conferences, it was, on balance, not unreasonable for Janssen to assume that the pens would be redistributed by the BRS within a reasonable period of time such that their provision would not be affected by changes introduced in the 2011 Code. The Appeal Board ruled that there had been no breach of the Code. The appeal on this point was successful.

An anonymous, non-contactable, renal nurse complained that Durogesic DTrans (fentanyl transdermal patch) branded pens had been included in the delegate bags at the BRS Meeting in Manchester, 14 to 16 May 2013. Durogesic was marketed by Janssen and was indicated in adults in the management of chronic intractable pain, whether due to cancer or otherwise, and in the long-term management of severe chronic pain in children receiving opioid therapy from 2 years of age.

COMPLAINT

The complainant was surprised to see Durogesic branded pens in the delegate bags at the recent BRS Meeting. The complainant thought that pharmaceutical companies were no longer allowed to produce branded pens and that it was against the Code to do so.

When writing to Janssen, the Authority asked it to respond in relation to Clause 18.3 of the Code.

RESPONSE

Janssen submitted that based on recollections of employees involved at the time, the pens in question, which incorporated the Durogesic DTrans logo, were last ordered by Janssen in 2007. A photograph of the pen was provided.

An unspecified quantity of pens displaying the product logo had been donated to the BRS in 2010 after BRS requested practical support from pharmaceutical companies. The BRS secretariat believed the pens were received in March. Janssen regarded the pens as surplus to requirement at that time, and although Durogesic DTrans was not routinely used in renal medicine, the pens were considered potentially useful to the BRS. There was no promotional intent in the supply of these pens to the BRS.

Janssen first knew that the pens were in the conference bags on 16 May 2013, when one of its employees at the conference was alerted by an employee of another pharmaceutical company. The Janssen employee immediately spoke to a representative of the BRS secretariat. It was pointed out that the conference brochure contained an acknowledgement that the pens were donated by Janssen in 2010 (the relevant page of the conference brochure was provided). Janssen had not been consulted about this acknowledgement in the conference brochure.

Janssen explained that it had a promotional stand in the exhibition area of the BRS conference which promoted Eprex (epoetin alfa). No pens or other promotional items had been provided at this stand.

Janssen submitted that it had not been consulted about placing the pens in the conference bags for the 2013 BRS conference in Manchester, nor had it given permission for the BRS to do so. The BRS

confirmed in a letter to Janssen dated 18 June 2013 that: 'The pens were supplied by Janssen UK in 2010. These remained unused in storage and a decision was made to place them in this year's delegate bags rather than throw them out. The company themselves were not aware this was occurring and

at no time were party to the decision to place these pens in the bags'.

The relevant job-bag, which Janssen assumed had been raised in 2007 when the pens were last ordered, had been destroyed in accordance with its routine records management policy, so it was unable to produce the certificate used to approve the pen.

In summary, Janssen submitted that the pens had been donated to the BRS in 2010 and had been placed in the conference bags by the BRS unbeknown to Janssen. Janssen stated that its actions had at all times been compliant with the Code given the circumstances outlined above and did not believe there had been a breach of Clause 18.3.

PANEL RULING

The Panel noted that in March 2010, an unspecified quantity of the branded pens had been donated to the BRS following a request for practical support from the industry. The Panel assumed that given their subsequent provision in delegate bags, Janssen must have donated a large number of pens and so it was not unreasonable to expect that the BRS would distribute such items to its members. The Panel noted Janssen's submission that there was no promotional intent in the supply of the pens to the BRS but considered that given the product logo, they could not be considered as anything other than promotional aids. When they were donated, branded pens were acceptable promotional aids under the 2008 Code. The Panel queried, however, whether the branded pens at issue should have been donated to the BRS at all given Janssen's submission that Durogesic DTrans was not routinely used in renal medicine. In that regard the Panel noted that the current summary of product characteristics (last revised 14 May 2013), available on the electronic Medicines Compendium website, recommended that if patients with renal impairment received Durogesic DTrans, they should be observed carefully for signs of fentanyl toxicity and the dose reduced if necessary. The Panel further noted that the 2011 Code (effective from 1 January, 2011 but with a transition period until 30 April, 2011) onwards prohibited the use of branded pens as promotional aids.

The Panel noted that branded pens, donated in 2010 by Janssen to the conference organisers, had been distributed in the delegate bags at the BRS meeting in Manchester in 2013. The Panel noted Janssen's submission that it first knew about the provision of the pens on 16 May via a colleague from another pharmaceutical company. In that regard the Panel noted that the conference brochure clearly stated that the pens had been donated by Janssen in 2010 and it queried how Janssen did not apparently see that statement and thus know about the provision of the pens before being alerted to the fact by a third party on the last day of the conference. The Panel noted that the provision of branded pens was no longer acceptable under the Code. A breach of Clause 18.3 was ruled. This ruling was appealed by Janssen.

APPEAL FROM JANSSEN

Janssen submitted that when it donated the branded pens to the BRS in early 2010, the Code in force at that time did not prohibit the provision of such branded items. In that regard the company's actions had been appropriate and consistent with the relevant Code. The ownership and control of the pens passed to the BRS and Janssen played no further role in deciding to what use the pens would be put.

Janssen submitted that the BRS had confirmed in writing that Janssen was not consulted about its decision to place the pens, which it had in storage, in the delegate bags for its conference held in May 2013.

APPEAL BOARD RULING

The Appeal Board noted from the Janssen representatives at the appeal that approximately 5,000 pens displaying the Durogesic DTrans product logo had been donated to the BRS in 2010 after BRS had requested practical support from pharmaceutical companies. Janssen envisaged that the pens would be used for BRS meetings including the annual conference in 2010 which according to BRS had approximately 1,500 attendees. The company assumed that the pens would be distributed over 2 years including the 2011 annual conference held in the spring. The Appeal Board noted the submission that the pens would also have been distributed at smaller meetings. The Appeal Board noted that following the donation in 2010 there had been no further discussion between the BRS and Janssen regarding the pens. The Appeal Board noted that, in response to a question, the BRS submitted that it had other sponsors for its 2011 and 2012 conferences. In the absence of a sponsor in 2013 it unilaterally decided to retrieve the pens from storage for use at its conference.

The Appeal Board noted that prior to the 2011 Code (effective from 1 January, 2011 but with a transition period until 30 April, 2011) pens with brand names could be distributed to health professionals under that edition of the Code. The Appeal Board considered that the prohibition of such pens introduced in the 2011 Code was not retrospective. However, it did not necessarily agree with Janssen's statement at the appeal hearing that as the industry had not been required to withdraw items given to individual health professionals the company could not have been expected to withdraw the pens given to an organisation such as the BRS.

The Appeal Board noted that the BRS conference brochure for 2013 stated that the pens had been donated by Janssen in 2010. The Appeal Board noted from the Janssen representatives at the appeal that its representative at the 2013 BRS conference had not seen the delegate pack including the brochure as he/she had downloaded the agenda from the internet. The Appeal Board was concerned that Janssen had not seen the conference brochure given it had a promotional stand at the conference. The Appeal Board noted that Durogesic was not routinely used in renal patients.

The Appeal Board considered that a large number of pens had been donated in 2010 and these needed to be used by the end of the transition period, ie 30 April 2011. The Appeal Board noted that whilst Janssen had donated the pens to BRS it was not thereby absolved of all responsibility under the Code in relation to their future use. Although it was concerned at the large number donated for redistribution, it considered that given the number of attendees at conferences, it was, on balance, not unreasonable for Janssen to assume that the pens would be redistributed by the BRS within a reasonable period of time such that their provision would not be affected by changes introduced in the 2011 Code. The Appeal Board ruled that there had been no breach of Clause 18.3. The appeal on this point was successful.

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