CASE AUTH/2870/8/16

VOLUNTARY ADMISSION BY JANSSEN

Trevicta advertisements

Janssen-Cilag voluntarily admitted breaches of the Code in relation to a number of Trevicta (paliperidone palmitate 3 monthly) journal advertisements placed during July and August 2016. Trevicta, a 3-monthly injection, was indicated for the maintenance treatment of schizophrenia in adults who were clinically stable on 1-monthly paliperidone palmitate injectable product.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Janssen.

Janssen explained that the advertisements were two page advertisements in which the prescribing information appeared overleaf, however the reference to where it could be found was missing, which was a breach of the Code. This was not picked up in the certification process.

Janssen submitted that the job bags had erroneously been uploaded into Zinc as digital job bags whereas the advertisements were in fact both digital and hard copy. This error meant that the journal advertisements were only electronically certified and not also certified in their final hardcopy form and so Janssen did not pick up on the missing prescribing information location reference. Janssen considered that the failure to certify the final form of the hardcopy advertisements also amounted to a breach of the Code.

The details submitted by Janssen are given below.

The Panel noted that the two page advertisements in question had prescribing information overleaf on the second page but the reference to where to find it was missing from the first page. A breach of the Code was ruled as acknowledged by Janssen.

The Panel noted Janssen's admission that the journal advertisements were only electronically certified and not also certified in their final hardcopy form. The Panel thus ruled a breach of the Code as acknowledged by Janssen.

Janssen-Cilag Ltd voluntarily admitted breaches of the Code in relation to four Trevicta (paliperidone palmitate 3 monthly) advertisements (ref PHGB/XEP/0516/0022, PHGB/XEP/0516/0022a, PHGB/XEP/0516/0022b, and PHGB/XEP/0616/0015) which it placed during July and August 2016. Trevicta, a 3-monthly injection, was indicated for the maintenance treatment of schizophrenia in adult patients who were clinically stable on 1-monthly paliperidone palmitate injectable product.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Janssen.

VOLUNTARY ADMISSION

Janssen stated that the advertisements were all two page advertisements in which the prescribing information appeared overleaf; in July they were published in The Commissioning Review, the BMJ, Nurse Prescribing, Prescriber and the British Journal of Mental Health Nursing, in August they appeared in the British Journal of Psychiatry and Progress in Psychiatry.

Janssen stated that on 1 August its media buyer alerted the healthcare digital agency, which in turn alerted Janssen, that the reference to where the prescribing information could be found was missing from the journal advertisements listed above. The absence of the prescribing information location reference had unfortunately not been picked up in Janssen's copy approval and certification process. The prescribing information appeared overleaf in the four printed advertisements and Janssen admitted a breach of Clause 4.7. Janssen stated that it had elected to contact the PMCPA proactively about this incident and to date had not received any complaints from recipients of the journals nor fellow ABPI members.

After performing an internal review, Janssen found that the job type field was incorrect; the job bags had erroneously been uploaded into Zinc as digital job bags. The advertisements were in fact both digital and hard copy, rather than just digital as per the job bags submitted. Unfortunately, due to this error at the Zinc upload stage, the journal advertisements were only electronically certified and not also certified in their final hardcopy form. Although no changes were made to the advertisements from the electronic certification stage to the hardcopy stage, unfortunately it meant that Janssen also missed the opportunity to pick up on the missing prescribing information location reference at final hardcopy certification stage. Janssen considered that the failure to certify the final form of the hardcopy advertisements amounted to a breach of Clause 14.1.

Janssen stated that it had a clear copy approval process in place but during this process, steps were completed incorrectly. Following its review, Janssen was satisfied that it was an isolated incident of human error that occurred during the copy approval initiation stage, due to an incorrect job bag item field being selected in Zinc.

Timelines

1 August – Janssen was first made aware of the absence of a reference to the location of prescribing information on the advertisements in question by teleconference outside of working hours by its digital healthcare agency

Confirmation received in writing from its digital healthcare agency and proposed actions. Although an internal Janssen error, additional checks were agreed with the agency for implementation - moving forward the printers would schedule a colour proof for each advertisement that was printed so that both the digital healthcare agency and printers could see the positioning of the artwork and do a final check on the colour quality and content in final output format.

2 August –The job bags listed above were withdrawn from Zinc and cancelled.

New artwork was created under a successor job bag for the advertisements with a reference to the prescribing information location included

3 August – Copy of deletion reports received: Janssen's media buyer provided a copy of deletion reports from each of the journals that had received an advertisement without a reference to the prescribing information location, ensuring that it did not run the advertisements again without receiving new files first.

Janssen confirmed that the prescribing information included with the advertisements was correct and up-to-date therefore patient safety had not been compromised. Janssen had reminded all individuals involved of their responsibilities in the copy procedure process and the Code requirements related to two page advertisements when the prescribing information was located overleaf.

Janssen submitted that it took its responsibilities under the Code very seriously and deeply regretted the errors described above.

RESPONSE

Janssen submitted that it had no further comments in relation to the requirements of Clauses 4.7 and 14.1.

PANEL RULING

The Panel noted that Clause 4.7 stated that in the case of a printed journal advertisement where the prescribing information appeared overleaf, at either the beginning or the end of the advertisement, a reference to where it could be found must appear on the outer page of the other page of the advertisement in a type size such that a lower case 'x' was no less than 2mm in height. The Panel noted that the four advertisements in question placed in seven journals during July and August 2016 were two page advertisements in which the prescribing information appeared overleaf on the second page. The reference to where the prescribing information could be found as required by Clause 4.7 was missing from the first page and a breach of that Clause was ruled as acknowledged by Janssen.

The Panel noted that the supplementary information to Clause 14.1 stated that when certifying material where the final form was to be printed companies could certify the final electronic version of the item to which no subsequent amendments would be made. When such material was printed the company must ensure that the printed material could not be used until any one of the company's signatories had checked and signed the item in its final form. In such circumstances the material would have two certificates and both must be preserved. The Panel noted Janssen's admission that the journal advertisements were only electronically certified and not also certified in their final hardcopy form. The Panel thus ruled a breach of Clause 14.1 as acknowledged by Janssen.

Complaint received **10 August 2016**

Case completed **23 August 2016**