CASE AUTH/2413/6/11

VOLUNTARY ADMISSION BY LEO

Promotion of Xamiol to the public

Leo Pharma advised that a film clip which demonstrated the application of Xamiol Gel (calcipotriol/betamethasone) on scalp psoriasis had been included on a DVD produced by Biogen Idec and distributed to health professionals and patients. In accordance with the Constitution and Procedure for the Prescription Medicines Code of Practice Authority, the Director treated the matter as a complaint. (The Director also took the matter up with Biogen Idec – see Case AUTH/2415/6/11).

Biogen Idec informed Leo that a Tysabri (natalizumab) patient DVD had been distributed that contained this film clip. The DVD was originally approved in April 2010 and DVDs without any error were produced by one production company. In March 2011 production was switched to a new agency and DVDs were produced which contained the Xamiol film clip. Leo had been informed that Biogen Idec would recall all the DVDs from health professionals and representatives but it did not plan a recall from patients. The Xamiol film clip in question arrived at the agency in December 2010 from Leo's Head Office in Denmark. Leo's Head Office had a confidentiality agreement with the agency which included instructions for destruction of materials.

The detailed response from Leo is given below.

According to Leo, Biogen Idec had explained that the video clip had appeared on its DVD as a result of an error post-certification at the agency. The Panel noted that the agency had the video clip as a result of its contract with Leo's headquarters.

The DVD in question had been distributed by Biogen Idec to patients. Leo's prescription only medicine had thus been promoted to the public and the Panel ruled a breach of the Code.

The Panel considered that Leo had been badly let down by the agency. Overall the Panel considered that Leo had not failed to maintain high standards and no breach of the Code was ruled. Consequently, the Panel ruled no breach of Clause 2.

Leo Pharma advised that a Xamiol (calcipotriol/betamethasone) film clip had appeared on a DVD distributed by Biogen Idec Limited to patients. In accordance with Paragraph 5.6 of the Constitution and Procedure for the Prescription Medicines Code of Practice Authority, the Director treated the matter as a complaint.

The Director also took the matter up with Biogen Idec (Case AUTH/2415/6/11).

COMPLAINT

A film clip demonstrating the application of Xamiol Gel on scalp psoriasis included on a DVD produced by Biogen Idec Ltd and distributed to health professionals and patients had recently come to Leo's attention.

Biogen Idec informed Leo that a Tysabri (natalizumab) patient DVD had been distributed that contained a Xamiol film clip. Apparently, this piece was originally approved by Biogen Idec in April 2010 and DVDs without any error were produced by one production company. In March 2011 production of the Tysabri DVD was switched to a new agency which produced 1,014 DVDs containing the Xamiol production film clip; 760 of these DVDs were still in the warehouse. Of the remaining 254, Leo had been informed that Biogen Idec would recall all the DVDs from health professionals and representatives but it did not plan a recall from patients.

The Xamiol film clip in question arrived with the agency in December 2010 from Leo Head Office in Denmark. Leo's Head Office had a confidentiality agreement in place with the agency which included instructions for destruction of materials. A copy of the film clip on a DVD was provided.

When writing to Leo, the Authority asked it to respond in relation to Clauses 22.1, 9.1 and 2 of the Code.

RESPONSE

Leo stated that it became aware of the incident through a courtesy call from Biogen Idec on 15 June 2011. Biogen Idec advised that a promotional video clip of Xamiol had inadvertently been included on a Biogen Idec Tysabri patient DVD destined to be distributed to health professionals and patients.

Leo immediately started to contact those involved in the production of the Biogen Idec DVD to establish as many facts as possible and so determine the appropriate course of action to minimize any potential hazard to patients.

The Xamiol video clip in question was sent to the agency in November 2010 by Leo Head Office in Denmark. It had never been used in the UK.

On 16 June Leo contacted both parties known to have been involved in the production of the Biogen DVD, the agency and Biogen Idec.

Leo requested and obtained on 17 June a video clip of Xamiol as it appeared on the Biogen Idec DVD

but isolated from the Tysabri patient DVD. In the absence of the original defective DVD, Leo was unable to provide any further information on the point of integration of the Xamiol material. The Biogen Idec patient DVD contained the Xamiol video clip without the inclusion of prescribing information or adverse event reporting advice when given to health professionals and potentially promoted the product directly to patients.

Leo understood that 1,014 DVDs were produced in February 2011 by the agency, 760 were still in a warehouse, so the remaining 254 DVDs were assumed to have been distributed. The total number of defective DVDs was unknown. The agency suggested that all DVDs were defective since they would have all been made from the original master file. Biogen Idec suggested that the Xamiol material inclusion was only on very limited copies and suggested that the error occurred post certification during manufacture. In the absence of access to the master file of the Biogen Idec DVD, Leo had no means to estimate the actual number of defective DVDs. The company insisted that all DVDs be recalled and destroyed forthwith and requested a copy of the destruction certificate.

Corrective action proposed and initiated by Biogen Idec was that the DVD was recalled from health professionals and Biogen Idec representatives but not from patients. Leo did not know the timeline of the recall. Leo stated that its request for further information from Biogen Idec confirming the recall timeline and destruction, by 22 June remained unanswered.

Leo submitted that it had self reported the matter due to the risk of promotion to patients along with inadequate information alongside the product when provided to health professionals. Leo had no means of establishing where the items had been distributed and hence was unable to account for recall of each item.

Clause 22.1 prohibited advertising prescription only medicines to patients. As outlined above the Xamiol video clip was inadvertently included in the Tysabri patient DVD, without any permission from Leo to do so or Leo having any knowledge of this use of the Xamiol clip. Leo believed that this fact, together with its request for immediate recall and destruction of all defective materials, demonstrated that it was not in breach of Clause 22.1 of the Code.

Leo was confident that it had taken all steps possible and necessary to ensure that the Xamiol promotional material distributed without its knowledge was recalled and destroyed. Moreover, it had made a voluntary submission about the matter to ensure transparency in all its promotional activities, therefore maintaining the high standards for the promotion of medicines expected from pharmaceutical companies under Clause 9.1.

To ensure that patient safety or patient health was not compromised as outlined in Clause 2, Leo insisted on the recall of all defective DVDs from patients not just health professionals as suggested by Biogen Idec. Leo submitted that this demonstrated its commitment to the Code as a whole and supported its understanding that Leo's actions specifically demonstrated it did not breach Clause 2.

PANEL RULING

The Panel noted that Clause 22.1 prohibited the promotion of a prescription only medicine to the public. Leo explained that the Xamiol video clip had been sent directly to the UK agency by Leo's headquarters in Denmark. The video clip at issue had never been distributed by Leo in the UK. However, given that the DVD in question was distributed in the UK, albeit by a different company, the Panel considered that Leo, based in the UK, was responsible for this matter under the Code.

According to Leo, Biogen Idec had explained that the video clip had appeared on its DVD as a result of an error post-certification at the agency. The Panel noted that the agency had the video clip as a result of its contract with Leo's headquarters. It was a well established principle that a company was responsible for the acts or omissions of its agents or third parties. If this were not the case companies would be able to rely on such acts or omissions as a means of circumventing the requirements of the Code. Leo was thus responsible for the acts or omissions of the agency in relation to the video clip.

The DVD in question had been distributed by Biogen Idec to patients. Leo's prescription only medicine had thus been promoted to the public and the Panel ruled a breach of Clause 22.1.

The Panel acknowledged the corrective action taken promptly by Leo once it had been informed by Biogen Idec of the error. The Panel noted that a confidentiality agreement had been in place between Leo's headquarters and the agency which included instructions for destruction of materials. The Panel had not seen a copy of the agreement nor did it know whether a certificate of destruction had been requested by Leo's headquarters. In any event, the Panel considered that Leo had been badly let down by the agency. Overall the Panel considered that Leo had not failed to maintain high standards and no breach of Clause 9.1 was ruled. Consequently, the Panel ruled no breach of Clause 2.

Proceedings commenced	**24 June 2011**
Case completed	**5 August 2011**