

ALMIRALL/DIRECTOR v LEO

Alleged breach of undertaking

Almirall alleged that two Leo Pharma advertisements for Picato (ingenol mebutate) gel, published in March and April 2013 breached the undertaking given by Leo in Case AUTH/2583/3/13.

The case was taken up by the Director as the Authority was responsible for ensuring compliance with undertakings.

Although Leo had changed the advertisements, Almirall alleged that the new advertisements remained misleading and exaggerated. Failing to comply with an undertaking brought discredit upon, or reduced confidence in, the pharmaceutical industry and a breach of Clause 2 was also alleged.

The detailed response from Leo is given below.

The Panel noted that an undertaking was an important document. It included an assurance that all possible steps would be taken to avoid similar breaches of the Code in future. It was very important for the reputation of the industry that companies complied with undertakings.

The Panel noted that the two advertisements identified by Almirall were not new material prepared by Leo subsequent to Case AUTH/2583/4/13. They were part of Leo's campaign for Picato which predated the undertaking given in Case AUTH/2583/4/13 by Leo on 4 April. Leo submitted that the advertisements at issue were caught by that undertaking and they had thus been withdrawn. The copy deadlines for the publications identified by Almirall predated both the notification of the Panel's ruling in Case AUTH/2583/4/13 (25 March) and the undertaking.

Noting the date of the undertaking and copy deadlines for the publications in question the Panel considered that Leo had not failed to comply with its undertaking given in the previous case and ruled no breach of the Code including Clause 2.

Almirall Limited alleged that two advertisements (refs 4340a/00016(1)b and 4340a/0006(1)a) for Picato (ingenol mebutate) gel, breached the undertaking given by Leo Pharma in Case AUTH/2583/3/13.

Almirall noted that the advertisements had been published in the BMJ (23/3/13 and 30/3/13), MIMS (April 2013), GP magazine, Dermatological Nursing magazine and Guidelines in Practice.

Picato was indicated for the cutaneous treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis in adults.

The case was taken up by the Director as the Authority was responsible for ensuring compliance with undertakings.

COMPLAINT

Almirall noted that both advertisements at issue were circulated in the medical press by Leo, subsequent to the Panel's ruling of 25 March 2013 in Case AUTH/2583/3/13.

Almirall noted that although Leo had changed the advertisements found to be in breach, the newly worded advertisements remained misleading and exaggerated, and thus did not reflect the guidance and stipulations given in the Panel's ruling.

Almirall noted that both advertisements featured the headline 'Announcing the arrival of Picato The only 2 or 3 day patient-applied actinic keratosis treatment' despite the Panel's ruling in the previous case that:

'The Panel noted that Picato was indicated for the cutaneous treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis in adults. The headline claim, however, only referred to actinic keratosis without noting the licence restriction. It appeared that Picato could treat any type of actinic keratosis which was not so. In that regard the Panel did not consider that the advertisement encouraged the rational use of the medicine. The provision of the indication in full in the prescribing information did not negate the otherwise misleading impression. A breach of Clause 7.10 was ruled.'

Almirall also noted that in Case AUTH/2583/3/13 the Panel further stated that:

'... The claim together with the image of the high speed train might be taken to relate to the speed of effect of Picato. In that regard the Panel noted that the optimum effect of treatment could only be assessed approximately 8 weeks (56 days) after treatment. The Panel considered that the claim was exaggerated as alleged. A breach of Clause 7.10 was ruled.'

Given the above, Almirall alleged that with its new advertisements Leo had failed to comply with its undertaking in breach of Clause 25.

Almirall further alleged that Leo's distribution of such advertisements, even after a clear ruling and guidance from the PMCPA brought discredit upon, or reduced confidence in, the pharmaceutical industry in breach of Clause 2.

RESPONSE

Leo submitted that the complaint related to advertisements that were submitted to journals and/or were in the process of being published before the ruling in Case AUTH/2583/3/13.

Leo provided details of the copy deadlines for each publication which were between 1 and 19 March 2013. The publication dates were mostly in March other than MIMS April. Leo submitted that the copy deadline for each of the publications cited by Almirall fell before the date of the original ruling in Case AUTH/2583/3/13 on the 25 March. Therefore, it would have been impossible to stop the publication of the advertisements in these journals and many were already circulated before the ruling.

Leo noted that Almirall had advertisements in some of the same publications and so should have known the publication/copy dates.

Leo stated that, contrary to Almirall's view, it had taken the recent breach very seriously and, on the day that it was notified of the Panel's ruling, 25 March, it withdrew further print copies of all advertisements, even though there had been no specific complaint against the advertisement that was in use at that time. Leo submitted that it had adhered to its own rigorous internal standards and timelines for the recall (documented through standard operating procedures).

Work then began on a new version of the advertisement and took into account the areas where the company was previously found in breach and also addressing the Panel's concerns on some areas where it was not found in breach.

Leo reiterated, in full support of the PMCPA's ruling, that appropriate measures were taken to withdraw and amend the Picato advertisement.

PANEL RULING

The Panel noted that an undertaking was an important document. It included an assurance that all possible steps would be taken to avoid similar breaches of the Code in future. It was very important for the reputation of the industry that companies complied with undertakings.

The Panel noted that the two advertisements identified by Almirall were not new material prepared by Leo subsequent to Case AUTH/2583/4/13. They were part of Leo's campaign for Picato which predated the undertaking given in Case AUTH/2583/4/13 by Leo on 4 April. Leo submitted that the advertisements at issue were caught by that undertaking and they had thus been withdrawn. The copy deadlines for the publications identified by Almirall predated both the notification of the Panel's ruling in Case AUTH/2583/4/13 (25 March) and the undertaking. It was thus not possible for Leo to prevent their publication.

Noting the date of the undertaking and copy deadlines for the publications in question the Panel considered that Leo had not failed to comply with its undertaking given in the previous case and ruled no breach of Clause 25 and consequently no breach of Clause 2.

Complaint received **23 April 2013**

Case completed **17 May 2013**