

HEALTH PROFESSIONAL v TOR GENERICS

Advertisement in The Big Issue

A health professional complained that a Tor Generics advertisement which included a pack shot of, *inter alia*, Tor-Bac 5ml in The Big Issue magazine, advertised an injection, and thus a prescription only medicine (POM) to the public in breach of the Code.

The detailed response from Tor Generics is given below.

The Panel noted the company's submission that once licensed Tor-Bac saline solution for injection would be a POM; the licence was pending. The Code prohibited the promotion of POMs to the public. Although the company was aware of its likely classification pending grant of Tor-Bac's marketing authorisation the product was not classified as a POM when the advertisement at issue was published. On this narrow technical point the Panel ruled no breach of the Code.

The Panel, however, considered that the inclusion of the Tor-Bac product pack in an advertisement aimed at the general public prior to the grant of its marketing authorization and when the company knew that it would be classified as a POM meant that high standards had not been maintained; a breach of the Code was ruled.

The Panel considered that the advertisement in The Big Issue in March 2017 promoted Tor-Bac to the public prior to the grant of its marketing authorization which was expected in June 2017. The Panel noted the company's explanation that the packshot had been provided by mistake. In the Panel's view the publication of the advertisement demonstrated a lack of care and awareness of the Code on matters that reflected UK law. The Panel considered that Tor Generics had thus brought discredit upon and reduced confidence in the pharmaceutical industry and a breach of Clause 2 was ruled.

A health professional complained about an advertisement issued by Tor Generics Ltd and published in The Big Issue, 20-26 March 2017. The advertisement provided by the complainant included pack shots of Vitamin D3 capsules, Vitamin A capsules and Tor-Bac 5ml which was described as 'Bacteriostatic saline solution for injection'.

COMPLAINT

The complainant explained that there were no general sale or over-the-counter injectable medicines in the UK. Hence normal saline for injection must be a prescription only product. As The Big Issue magazine was sold by street vendors to the public, the complainant alleged that an advertisement in it for injectable saline was an advertisement for a prescription only medicine to the public, in breach of Clause 26.1.

When writing to Tor Generics the Authority asked it to consider the requirements of Clauses 26.1, 9.1 and 2 of the Code.

RESPONSE

Tor Generics confirmed that Tor-Bac would be a prescription only medicine; the licence was pending with the Medicines and Healthcare products Regulatory Agency (MHRA). Tor Generics submitted that Tor-Bac was manufactured in the EU and was due to launch in June 2017. Due to an oversight on Tor Generics' part, it was included ahead of launch in error, when jpegs for other products were sent for the advertisement compilation and the advertisement was placed in The Big Issue. Tor-Generics stated that it would withdraw the advertisement or 'public information' from The Big Issue from the next edition (end of April) and provided assurance that it would not include the product going forward until all terms via the ABPI had been adhered to. According to Tor-Generics, Tor-Bac was a saline solution aimed at the dental market and was not generally perceived as a generic for generic sale.

Tor Generics confirmed that the jpeg had been taken off any future advertisements in The Big Issue and would not be advertised anywhere in the public press until a licence was obtained and even then only in suitable medical journals.

The company provided a copy of its revised advertisement which referred to Tor Generics and its website. This advertisement did not mention by name or refer to any products.

It appeared from correspondence with a third party that the jpeg for the advertisement at issue was placed by mistake and that Tor Generics currently wanted to keep the advertisement just as a picture of Glastonbury Tor with the company's website address. The company stated that it was happy to support The Big Issue with advertising until its contract finished shortly, but it would be wiser to show no pictures of its products at all.

The company confirmed that the advertisement was sent in error and had been withdrawn as indicated in emails provided. A copy of an email dated 4 April was provided in which the typesetter for The Big Issue was asked to remove the 3 pack shots from the advertisement. In addition, Tor Generics stated that having thought again it might be wise to remove all pack shots for the remaining 2/3 advertisements left in the 12 month agreement.

In a further email to the ABPI, Tor Generics stated that Tor-Bac was not on the market yet. The company submitted that there was not much of a case to answer as Tor Generics was a tiny company and the

product was not available in the UK. A jpeg was loaded incorrectly, and the advertisement was picked up in The Big Issue.

PANEL RULING

The Panel noted Tor Generic's submission that Tor-Bac saline solution for injection would be a prescription only medicine, the licence was pending with the MHRA and the product was due to launch in June 2017. Clause 26.1 prohibited the promotion of prescription only medicines to the public. Although the company was aware of its likely classification pending grant of its marketing authorisation the product was not classified as a prescription only medicine when the advertisement at issue was published. On this narrow technical point the Panel ruled no breach of Clause 26.1 of the Code.

The Panel noted that Clause 3.1 which required that a medicine must not be promoted prior to the grant of the marketing authorization which permits its sale or supply had not been raised with the company as on receipt of the complaint it had not been apparent that the medicine was unlicensed. The Panel therefore made no rulings in that regard.

The Panel noted the requirements of Clauses 3.1 and 26.1. The Panel considered that the inclusion of the Tor-Bac product pack in an advertisement aimed at

the general public prior to the grant of its marketing authorization and when the company knew that it would be classified as a prescription only medicine meant that high standards had not been maintained; a breach of Clause 9.1 was ruled.

The Panel considered that the advertisement in The Big Issue in March 2017 promoted Tor-Bac to the public prior to the grant of its marketing authorization which was expected in June 2017. The Panel noted the company's explanation that this matter had arisen as a jpeg file had been provided to the journal by mistake. In the Panel's view the publication of the advertisement demonstrated a lack of care, and awareness of the Code on matters that reflected UK law. The Panel noted that the supplementary information to Clause 2 included promotion prior to the grant of a marketing authorization as an example of an activity that was likely to be in breach of that Clause. The Panel considered that Tor Generics had thus brought discredit upon and reduced confidence in the pharmaceutical industry and a breach of Clause 2 was ruled.

Complaint received **1 April 2017**

Case completed **9 June 2017**