CASE AUTH/2204/1/09

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY v ASTRAZENECA

Zoladex journal advertisement

The Medicines and Healthcare products Regulatory Agency (MHRA) alleged that a journal advertisement for Zoladex (goserelin), issued by AstraZeneca, was in breach of the Code because it included a reference to the MHRA. The advertisement, which gave AstraZeneca's perspective on a recent review of the class of medicines to which goserelin belonged, stated:

> **'The Medicines and Healthcare products Regulatory Agency (MHRA) recently reviewed the licence for goserelin 3.6 mg and 10.8 mg and updated the Summary of Product Characteristics (SmPC) to reflect these survival benefits. As such Section 5.1 of the goserelin SmPC details a wealth of survival data relating specifically to randomised controlled trials with goserelin.'**

The detailed response from AstraZeneca is given below.

The Panel noted that the Code prohibited reference in promotional material to, *inter alia*, the MHRA. The only exemption to this prohibition was if such reference was specifically required by the licensing authority. The MHRA had not specifically required AstraZeneca to include such a reference in its promotional material. The Panel therefore ruled a breach of the Code as acknowledged by AstraZeneca.

The Medicines and Healthcare products Regulatory Agency (MHRA) complained about a Zoladex (goserelin) advertisement (ref AZ-CZ000261b-ZOLU) issued by AstraZeneca UK Limited, which had appeared in The Pharmaceutical Journal, 17 January 2009 and included the following:

> 'The Medicines and Healthcare products Regulatory Agency (MHRA) recently reviewed the licence for goserelin 3.6 mg and 10.8 mg and updated the Summary of Product Characteristics (SmPC) to reflect these survival benefits. As such Section 5.1 of the goserelin SmPC details a wealth of survival data relating specifically to randomised controlled trials with goserelin.'

Zoladex was a leuteinising hormone releasing hormone analogue (LHRHa) indicated for certain types of cancer.

COMPLAINT

The MHRA alleged that reference in the advertisement to the MHRA was in breach of Clause 9.5 of the Code.

The MHRA referred to a previous case, Case AUTH/1794/2/06, involving Ipsen's product Decapeptyl (triptorelin) which had prompted AstraZeneca to contact the MHRA. The Therapeutic Review Group reviewed all LHRHas and amended the indications to ensure they were in accordance with current clinical guidelines and terminology.

The advertisement at issue gave AstraZeneca's perspective on the therapeutic review.

RESPONSE

AstraZeneca accepted that this genuine error was in breach of Clause 9.5 and unreservedly apologised to the MHRA. Measures had been taken to stop, where possible, any further publication of the advertisement at issue. The text would be amended. In addition, this case would be addressed at AstraZeneca's internal quarterly Code awareness training days.

AstraZeneca did not intend to suggest endorsement of Zoladex by the MHRA. The reference to the MHRA was intended to be a factual account of events and that this was a breach of Clause 9.5 was a genuine oversight.

AstraZeneca accepted that the therapeutic review was initially conducted to ensure that licences for the LHRHa class were in accordance with current clinical guidelines and terminology and that this followed a historical case. However, the additional changes to the Zoladex summary of product characteristics (SPC) to reflect survival benefits was agreed following further discussion with the MHRA after the initial class review. The advertisement referred to this most recent update of the SPC in July 2008.

AstraZeneca proposed to amend to, *inter alia*, remove all direct reference to the MHRA. The company would write directly to the MHRA to ensure that it agreed with the proposed amendments.

PANEL RULING

The Panel noted that Clause 9.5 prohibited reference in promotional material to, *inter alia*, the MHRA. The only exemption to this prohibition was if such reference was specifically required by the licensing authority. The MHRA had not specifically required AstraZeneca to include such a reference in its promotional material. The Panel therefore ruled a breach of Clause 9.5 as acknowledged by AstraZeneca.

Complaint received **27 January 2009**

Case completed **24 February 2009**