

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY v RECORDATI

Tradorec XI Leavepiece

The Medicines and Healthcare products Regulatory Agency (MHRA) complained about a Tradorec XL (tramadol) leavepiece issued by Recordati. Page three of the leavepiece featured a box headed 'MHRA advice:' followed by 'Prolonged Release preparations should be prescribed by brand, with no generic substitution'. The claim was referenced to 'Personal Communication. Recordati Pharmaceuticals Ltd'.

The MHRA stated that it had recently received a complaint which alleged there was no justification for the inclusion of the 'MHRA advice' on prescribing by brand in the leavepiece and that this was misleading. The MHRA alleged that reference to 'MHRA advice' was a clear breach of the Code and therefore referred this aspect to the Authority.

The Panel was extremely concerned to note that emails to the MHRA from Recordati had been sent by a consultant to the company who described himself in the emails as an independent pharmaceutical consultant without noting at the same time that he was writing on behalf of Recordati or any other pharmaceutical company. One email referred to tramadol. Neither of the emails sent to the MHRA referred to the proposed use of the information in promotional literature. The Panel considered that Recordati had not been transparent in its correspondence with the MHRA.

The Panel noted that the MHRA, without being told the intention behind the correspondence, had in effect given permission to the pharmaceutical consultant to show the email correspondence to health professionals. The MHRA had not specifically required Recordati to include such a reference in its promotional material, thus even if Recordati had fully informed permission from the MHRA it would nonetheless be unacceptable to mention the MHRA in promotional material. The Panel therefore ruled a breach of the Code.

The Medicines and Healthcare products Regulatory Agency (MHRA) complained about a Tradorec XL (tramadol) leavepiece (ref TRA06-0020) issued by Recordati Pharmaceuticals Ltd.

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COMPLAINT

The MHRA had recently received a complaint which alleged there was no justification for the inclusion of the 'MHRA advice' on prescribing by brand in the leavepiece and that this was misleading. The MHRA was minded to take the view that the leavepiece was misleading and in potential breach of Regulation 3A(3) of the Medicines (Advertising) Regulations 1994. It was currently investigating this case.

The MHRA alleged that reference to 'MHRA advice' was a clear breach of Clause 9.5 of the Code and therefore referred this aspect to the Authority.

RESPONSE

Recordati denied a breach of Clause 9.5 because it had explicit permission from the MHRA Information Centre to share its advice on the prescribing of modified/prolonged release preparations with NHS workers, including GPs; the leavepiece reflected that permission.

Recordati explained that before it launched Tradorec XL a consultant to the company emailed the MHRA Information Centre to ask if it had any advice on the prescribing of once daily formulations of tramadol. Two responses were received which although worded slightly differently were both clear that brand or invented names should be used when writing or prescribing modified/prolonged release preparations. The consultant emailed the MHRA Information Centre again to ask whether its reply could be shown to workers in the NHS. The reply confirmed that it could be.

Having been told that modified/prolonged release preparations should be prescribed by brand/invented name and having asked for and received permission from the MHRA to show this advice to workers in the NHS, Recordati believed it had complied with both the spirit and letter of Clause 9.5.

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 Panel was extremely concerned to note that the emails to the MHRA from Recordati had been sent by a consultant to the company who described himself in the emails as an independent pharmaceutical consultant without noting at the same time that he was

writing on behalf of Recordati or any other pharmaceutical company. One email referred to tramadol. Neither of the emails sent to the MHRA referred to the proposed use of the information in promotional literature. The Panel considered that Recordati had not been transparent in its correspondence with the MHRA.

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The MHRA had not specifically required Recordati to include such a reference in its promotional material, thus even if Recordati had fully informed permission from the MHRA, given the wording of Clause 9.5 it would nonetheless be unacceptable to mention the MHRA in promotional material. The Panel therefore ruled a breach of Clause 9.5.

Complaint received	10 August 2007
Case completed	6 September 2007
