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CASE AUTH/2082/1/08

DIRECTOR, MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY and a HOSPITAL PHARMACY MANAGER v RECORDATI

Tradorec XL 'Dear Dispensary Manager' letter

The Medicines and Healthcare products Regulatory Agency (MHRA) passed to the Authority a complaint which it had received from a hospital pharmacy manager. The complaint was about a 'Dear Dispensary Manager' letter for Tradorec XL (prolonged release tramadol) dated 29 June 2007 and sent by Recordati.

As the complaint involved an alleged breach of undertaking that aspect of it was taken up by the Director as it was the responsibility of the Authority itself to ensure compliance with undertakings.

The complainant noted that the letter stated that Tradorec XL should be prescribed by brand name as 'The MHRA advises that as a Prolonged Release product, it should not be substituted with any Sustained Release or Modified Release formulation, whether branded or generic'. The complainant did not think that the MHRA had made such a statement and as far as she knew, product specificity when prescribing related to products with varying bioavailability, eg diltiazem, theophylline and in certain other situations, such as prescribing of isosorbide mononitrate XL, it was best practice to prescribe by brand but not clinically significant to do so.

In its covering letter to the Authority, the MHRA stated that it was surprised to see the complaint given the outcome of Case AUTH/2034/8/07 and it asked the Authority to investigate.

The Panel noted that Case AUTH/2034/8/07 concerned a reference in a box headed 'MHRA advice' followed by 'Prolonged Release preparations should be prescribed by brand, with no generic substitution'. Case AUTH/2034/8/07 completed on 6 September when Recordati provided an undertaking not to refer to the MHRA in its promotional material unless specifically required to do so by the licensing authority following the Panel's ruling of a breach of the Code.

The Panel noted that there were differences between the present case and Case AUTH/2034/8/07. The statement at issue was different and read 'The MHRA advises that as a Prolonged Release product, it [ie Tradorec XL] should not be substituted with any sustained Release or Modified Release formulation, whether branded or generic'. The hospital pharmacy manager's allegation that the statement was incorrect as the MHRA had made no such product specific statement had not been considered before. Recordati considered that this allegation was covered by the previous case. The Panel noted the company's submission in the previous case and comment in the Panel ruling regarding email correspondence from the MHRA. The matter was further complicated in that irrespective of the MHRA's position on this point such references could not appear in promotional material. Nonetheless, in the present case, the Panel had to rule upon the complainant's allegation on this point and considered that high standards had not been maintained. A breach of the Code was ruled.

The Panel considered that the concerns raised by the MHRA had been dealt with in the previous case. A breach of the Code was ruled.

The letter at issue in the current case was dated 29 June 2007 and the complainant thought she had received it on 5 July 2007, well ahead of the undertaking provided by Recordati in September 2007. Thus the Panel decided there was no breach of the undertaking given in the previous case, Case AUTH/2034/8/07. The Panel ruled no breach of the Code.

The Medicines and Healthcare products Regulatory Agency (MHRA) passed to the Authority a complaint which it had received from a hospital pharmacy manager. The complaint concerned a 'Dear Dispensary Manager' letter (ref TRA06-0017) for Tradorec XL (prolonged release tramadol) dated 29 June 2007 and sent by Recordati Pharmaceuticals Ltd.

As the complaint involved an alleged breach of undertaking that aspect of it was taken up by the Director as it was the responsibility of the Authority itself to ensure compliance with undertakings.

COMPLAINT

The complainant noted that the letter stated that Tradorec XL should be prescribed by brand name as 'The MHRA advises that as a Prolonged Release product, it should not be substituted with any Sustained Release or Modified Release formulation, whether branded or generic'. Recordati cited references at the end of the letter (below the prescribing information) - there was no reference 3 there - so no reference to back up its statement.

The complainant queried the claim regarding the MHRA statement as quoted above. The complainant

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did not think that the MHRA had made such a statement and as far as she knew, product specificity when prescribing related to products with varying bioavailability, eg diltiazem, theophylline and in certain other situations, such as prescribing of isosorbide mononitrate XL, it was best practice to prescribe by brand but not clinically significant to do so.

In its covering letter to the Authority, the MHRA stated that it was surprised to see the complaint after the action the Authority had taken in Case AUTH/2034/8/07 and asked the Authority to investigate.

When writing to Recordati, the Authority asked it to respond in relation to Clauses 9.1 and 9.5 of the Code. The letter in question was dated 29 June 2007. If it had been sent after 6 September 2007, Recordati was also asked to respond in relation to Clauses 2 and 22 and explain the steps taken to comply with the undertaking given in relation to Case AUTH/2034/8/07.

RESPONSE

Recordati stated that the letter was sent to tell managers of dispensing practices about the Tradorec XL discount scheme.

Recordati noted that with regard to reference 3, this was included in the list of references although it was alongside reference 2, and not below it. This oversight was corrected in later versions of the prescribing information.

The reference to the MHRA in the letter was addressed in Case AUTH/2034/8/07 which concerned a leavepiece that had also referred to the MHRA. Following the Panel's ruling of a breach of the Code in that case, Recordati immediately took the steps necessary to comply with its undertaking in relation to that finding. This was not to use the leavepiece and any similar material.

Recordati noted that the complainant did not state when the material was received and as the complainant was not known to Recordati it had no way of tracing when it was sent. It appeared that the letter had either been received some months earlier or been severely delayed in the post.

With regard to Clause 9.1, Recordati believed it had maintained high standards. With regard to Clause 9.5, this had already been addressed in the earlier case and Recordati had implemented its undertaking at that time. With regard to Clauses 2 and 22, Recordati had every reason to believe that the letter was sent before 6 September 2007.

FURTHER INFORMATION FROM THE COMPLAINANT

In response to a request for further information the complainant stated that she could not recall the precise date when she received the letter at issue. Her best recollection would be 5 July 2007.

PANEL RULING

The Panel noted that the previous case, Case AUTH/2034/8/07, concerned a reference in a box headed 'MHRA advice' followed by 'Prolonged Release preparations should be prescribed by brand, with no generic substitution'. Case AUTH/2034/8/07 completed on 6 September when Recordati provided an undertaking not to refer to the MHRA in its promotional material unless specifically required to do so by the licensing authority following the Panel's ruling of a breach of the Code.

The Panel noted that there were differences between the present case and Case AUTH/2034/8/07. The statement at issue was different and read 'The MHRA advises that as a Prolonged Release product, it [ie Tradorec XL] should not be substituted with any sustained Release or Modified Release formulation, whether branded or generic'. The hospital pharmacy manager's allegation that the statement was incorrect as the MHRA had made no such product specific statement had not been considered before. Recordati considered that this allegation was covered by the previous case. The Panel noted the company's submission in the previous case and comment in the Panel ruling regarding email correspondence from the MHRA. The matter was further complicated in that irrespective of the MHRA's position on this point such references could not appear in promotional material (Clause 9.5). Nonetheless, in the present case, the Panel had to rule upon the complainant's allegation on this point and considered that high standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel considered that the concerns raised by the MHRA in relation to Clause 9.5 had been dealt with in the previous case. A breach of Clause 9.5 was ruled.

The letter at issue in the current case was dated 29 June 2007 and the complainant thought she had received it on 5 July 2007, well ahead of the undertaking provided by Recordati in September 2007. Thus the Panel decided there was no breach of the undertaking given in the previous case, Case AUTH/2034/8/07. The Panel ruled no breach of Clause 22 and hence Clauses 9.1 and 2.

Complaint received 21 January 2008

Case completed 3 March 2008