

CASE AUTH/3526/6/21

VOLUNTARY ADMISSION BY LEO

Broken prescribing information links on promotional Innohep emails

Leo Pharma UK voluntarily admitted that in promotional emails for Innohep (tinzaparin) sent out to UK health professionals, the links to the prescribing information were broken. Innohep was an anticoagulant indicated for the treatment and prophylaxis of thrombotic events in certain adults.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Leo.

Leo submitted that promotional emails for Innohep contained a URL hyperlink to the prescribing information on a website, www.innohep.co.uk, which was provided by way of a clear and prominent direct single click link.

Leo stated that on 8 March, a new website, which had merged www.innohep.uk and its sister website www.innohep.ie, was pushed live, and the previous websites taken down.

On 17 March, during approval of a new promotional email, it was noted that the URL hyperlink to the prescribing information was inactive as a result of being broken during the website upgrade work.

Leo stated that between 8 to 17 March, six promotional emails with broken prescribing information links were sent out and health professionals clicking on the links would have been unable to access the prescribing information during that time.

Leo admitted that the sending of a promotional email with broken prescribing information breached the requirement that prescribing information must be provided for all digital promotional material for a medicine either by inclusion in the material itself or by way of a clear and prominent direct single click link. Leo acknowledged responsibility for not checking the links following the website upgrade, and therefore regrettably voluntarily admitted breaches of the Code.

The detailed response from Leo is given below.

The Panel noted that each of the six email templates at issue was headed with: 'This is a promotional email intended for UK healthcare professionals only. Click here for adverse event reporting and prescribing information' or 'This is a promotional email from Leo Pharma. This event is intended for UK health professionals only. Click here for adverse events and prescribing information'.

The Panel noted Leo's submission that when the emails were approved for use, the 'Click here' link which connected to the website www.innohep.co.uk was active but that when that website was merged in March 2021 with www.innohep.ie and the now combined website went live, the link was broken, thus preventing readers from accessing the

prescribing information. The Panel noted that between 8 and 17 March 2021, six promotional emails with broken prescribing information links were sent out to UK health professionals.

The Panel noted that in the case of digital material, the prescribing information could be provided either in the digital material itself or via a clear and prominent direct single click link. The Panel noted that in the emails in question, that single click link was broken and breaches of the Code were ruled as acknowledged by Leo.

The Panel noted the circumstances of this case and considered that Leo would have been well advised to have tested the links to the new combined website at the outset, given that prescribing information was an important contributor to patient safety. In that regard, the Panel considered that high standards had not been maintained and a breach of the Code was ruled. Overall, the Panel did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and reserved for such. No breach of Clause 2 was ruled.

Leo Pharma UK voluntarily admitted that in promotional emails for Innohep (tinzaparin) sent out to UK health professionals, the links to the prescribing information were broken. Innohep was an anticoagulant indicated for the treatment and prophylaxis of thrombotic events in certain adults.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Leo.

VOLUNTARY ADMISSION

Leo submitted that promotional emails for Innohep, developed and used by members of the thrombosis business unit, contained a URL hyperlink to the prescribing information on a website, www.innohep.co.uk. In accordance with Clause 4.4 of the Code, the prescribing information was provided by way of a clear and prominent direct single click link.

Leo stated that on 8 March 2021, a new website, which had merged www.innohep.uk and its sister website www.innohep.ie, was pushed live, and the previous websites taken down.

On 17 March, during approval of a new promotional email, it was noted that the URL hyperlink to the prescribing information was inactive as a result of being broken during the website upgrade work. All promotional emails containing the broken prescribing information links were immediately withdrawn from use.

Leo stated that between 8 to 17 March, which was six working days, six promotional emails with broken prescribing information links were sent out to UK health professionals. Therefore, health professionals clicking on the links would have been unable to access the prescribing information during that time. Leo stated that it had had no complaints or feedback from health professionals on the matter.

Leo stated that marketing, digital and medical teams had been informed, and action taken to ensure that where website maintenance was required, there was mitigation to ensure that either the prescribing information remained accessible via the link, or if that was not possible, that any digital materials linking to prescribing information on the affected website were suspended from

use until the prescribing information was accessible and testing had verified that the links to the prescribing information were viable.

Leo admitted that the sending of a promotional email with broken prescribing information breached the requirement that prescribing information must be provided for all digital promotional material for a medicine either by inclusion in the material itself or by way of a clear and prominent direct single click link. Leo acknowledged responsibility for not checking the links following the website upgrade, and therefore regrettably voluntarily admitted breaches of Clauses 4.1 and 4.4.

When writing to Leo to advise it that the matter would be taken up as a complaint, the Authority asked it to provide any further comments it might have on the matter in relation to Clauses 4.1 and 4.4 and to also bear in mind the requirements of Clauses 9.1 and 2.

RESPONSE

Leo stated that with regard to the arrangements for checking links when certifying materials, the links would have been checked when the materials were certified - the links within the materials were 'clickable' and directed to the respective URL, even within the Veeva Promomats approval system. The links were working when the materials were certified in September 2020 and January 2021. However, the links stopped working in March 2021 ie well after certification.

Leo provided copies of the email templates and approval certificates in question.

PANEL RULING

The Panel noted that each of the six email templates at issue was headed with: 'This is a promotional email intended for UK healthcare professionals only. Click here for adverse event reporting and prescribing information' or 'This is a promotional email from Leo Pharma. This event is intended for UK health professionals only. Click here for adverse events and prescribing information'. One of the six email templates discussed cancer associated thrombosis guidelines, two discussed dosage and administration of Innohep and included a hyperlink to the Innohep SPC on the eMC website in the references section, and the remaining three emails invited health professionals to, or reminded them about, Innohep webinars.

The Panel noted Leo's submission that when the emails were approved for use in September 2020 and January 2021, the 'Click here' link which connected to the website www.innohep.co.uk was active but that when that website was merged in March 2021 with www.innohep.ie and the now combined website went live, the link was broken, thus preventing readers from accessing the prescribing information. The Panel noted that between 8 and 17 March 2021, six promotional emails with broken prescribing information links were sent out to UK health professionals. The Panel did not know how many health professionals each promotional email had been sent to; Leo made no submission in that regard.

The Panel noted that Clause 4.1 required prescribing information to be provided on all promotional material. Clause 4.4 stated that in the case of digital material, the prescribing information as required by Clause 4.1 could be provided either in the digital material itself or via a clear and prominent direct single click link. The Panel noted that in the emails in question that single click link was broken. Breaches of Clauses 4.1 and 4.4 were ruled as acknowledged by Leo.

The Panel noted the circumstances of this case and considered that Leo would have been well advised to have tested the links to the new combined website at the outset, given that prescribing information was an important contributor to patient safety. In that regard, the Panel considered that high standards had not been maintained. A breach of Clause 9.1 was ruled. The Panel noted Leo's submission that going forward, the links to prescribing information would be checked as a part of any website maintenance. Overall, the Panel did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and reserved for such. No breach of Clause 2 was ruled.

Complaint received 25 June 2021

Case completed 26 August 2021