

GENERAL PRACTITIONER v LILLY

Legibility of prescribing information

A general practitioner complained that the prescribing information on an advertisement for Bydureon (exenatide) was incredibly difficult to read.

The detailed response from Lilly is given below.

The Panel noted that the Code required prescribing information to be given in a clear and legible manner. Relevant supplementary information listed a number of factors which would help achieve clarity. The Panel considered that the prescribing information was on the limits of acceptability with regard to the contrast between text and background. However, on the whole, the Panel considered that, although not easy to read, the prescribing information did not fail to comply with the Code and no breach was ruled. The Panel noted Lilly's intention to change the combination of font, colour and background in future material.

A general practitioner complained about a Bydureon (exenatide) outsert that was attached to the July/August 2011 edition of Practical Diabetes. Bydureon, marketed by Eli Lilly and Company Limited, was an oral add-on therapy indicated in type 2 diabetes in adults who had not otherwise achieved adequate glycaemic control on maximally tolerated doses of other oral anti-diabetic agents.

COMPLAINT

The complainant alleged that the prescribing information was incredibly difficult to read and in his opinion contravened Clause 4.1 of the Code, which stated that 'a clear style of type should be used' and 'dark print and light background is preferable'.

The complainant stated that, ironically, the same journal had contained an article entitled 'Consumers find food labels confusing and too small to read'; it appeared the pharmaceutical industry and the food industry had a lot in common.

RESPONSE

Lilly considered that the prescribing information met the requirements of the Code; the text was of an appropriate height, spacing, style and legibility and thus the prescribing information had been provided in a clear and legible manner. Lilly denied a breach of Clause 4.1.

Notwithstanding the above, Lilly submitted that it would change the combination of font, colour and

background of the prescribing information in future materials.

PANEL RULING

The Panel noted that Clause 4.1 required that prescribing information be given in a clear and legible manner. The supplementary information to Clause 4.1, Legibility of Prescribing Information, listed the following recommendations to help achieve clarity:

- type size should be such that a lower case letter 'x' was no less than 1mm in height
- lines should be no more than 100 characters in length, including spaces
- sufficient space should be allowed between lines to facilitate easy reading
- a clear style of type should be used
- there should be adequate contrast between the colour of the text and the background
- dark print on a light background was preferable
- boldening headings and starting each section on a new line aided legibility

The Panel noted that the prescribing information in question met these requirements in relation to the number of characters per line, spacing, type style and emboldened headings. The Panel noted that most of the text met the sizing requirements but that where C_{max} and T_{max} were referred to in the 'Interactions' section, the 'max' subscript was not legible. However, given the context in which these appeared, the Panel considered that the reader would know what the subscript was.

The Panel noted that the prescribing information at issue consisted of grey text on a white background. This was not helpful. The Panel noted the recommendation in the supplementary information in relation to the contrast between text and background. The Panel considered that the prescribing information was on the limits of acceptability in this regard. However, on the whole, the Panel considered that, although not easy to read, the prescribing information did not fail to comply with the requirements of Clause 4.1 and ruled no breach of that clause. The Panel noted Lilly's intention to change the combination of font, colour and background in future material.

Complaint received	10 August 2011
Case completed	7 September 2011