Case AUTH/3274/10/19

COMPLAINANT v DIURNAL

Promotion of pipeline products

A complainant who described him/herself as a 'concerned UK health professional', noted that one webpage on Diurnal Limited's corporate website, in the section aimed at health professionals, referred to current products and those in the company's pipeline. A downloaded copy of the page which showed a table of data headed 'Diurnal's drug-development pipeline – Europe' was provided. The complainant alleged that the table constituted pre-licence promotion and that there was no prescribing information or generic names for licensed products.

The detailed response from Diurnal is given below.

In the Panel's view, it was not necessarily unacceptable for a company to refer in general terms to its pipeline products on its corporate website, however language, context, location, layout, intended audience and overall impression were important factors. Such references should not otherwise constitute promotion of an unlicensed medicine.

The Panel noted that the webpage at issue was in the health professionals' section of Diurnal's website. If health professionals wanted to find out about Diurnal medicines they had to visit the section of the website which detailed 'Products and Pipeline' – the two were not separate. The table of data which detailed five products in Diurnal's European drug development pipeline, was within the 'Clinical Trials' section of 'Products and Pipeline'; one of the products listed, Alkindi (hydrocortisone granules in capsules for opening), had been licensed for paediatric adrenal insufficiency in 2018. Four other products were listed together with the indication for which they were being developed, their clinical trial status and the expected approval dates – variously 2021, 2023 and 'TBC' (to be confirmed).

The Panel noted from the downloaded page provided by Diurnal that the table of data was introduced by, *inter alia*, 'Diurnal is dedicated to bringing effective, high quality products to the global market for the life-long treatment of chronic endocrine conditions'; this implied that the medicines listed were effective and high quality. In addition, the indications were stated. In the Panel's view, the webpage, which was directed at health professionals and was within a section of the website that promoted the company's licensed medicine, was promotional and designed to elicit interest in both Diurnal's licensed medicine and in its pipeline products. The Panel considered that the information about the unlicensed medicines constituted promotion of those medicines and a breach of the Code was ruled.

The Panel further considered that the information provided about Alkindi (product name and indication (paediatric adrenal insufficiency)) on a promotional section of the website, was promotional. The Code required that in digital promotional material, the prescribing

information must be included in the material itself or by way of a clear and prominent direct single click link. There was no link to the Alkindi prescribing information and the non-proprietary name had not been provided. Breaches of the Code were ruled.

The Panel noted its rulings above and considered that high standards had not been maintained. A breach of the Code was ruled.

The Panel considered that the response from Diurnal showed a poor understanding of the requirements of the Code. In the Panel's view the restrictions around how, when and what information could be provided about pipeline products and the definition of what constituted promotion of licensed medicines were such that companies should not combine the two. The promotion of a medicine prior to the grant of its marketing authorization was listed in the Code as an activity likely to be ruled in breach of Clause 2 – a sign of particular censure. The company had failed to recognise that the information it had provided was promotional. The Panel considered that the company's conduct in introducing, formatting and providing the information that it had, fell short of competent care; unlicensed medicines had been promoted to health professionals. A breach of Clause 2 was ruled.

A complainant who described him/herself as a concerned UK health professional, complained about Diurnal Limited's corporate website and in particular the section aimed at health professionals.

COMPLAINT

The complainant noted that one webpage referred to both current products and those in the company's pipeline. A downloaded copy of the page which showed a table of data headed 'Diurnal's drug-development pipeline – Europe' was provided. The complainant alleged that the table constituted pre-licence promotion and for licensed products there was no prescribing information or generic names.

When writing to Diurnal, the Authority asked it to consider the requirements of Clauses 2, 3.1, 4.1, 4.3 and 9.1 of the Code.

RESPONSE

Diurnal submitted that it had not promoted any unlicensed medicine and thus denied a breach of Clause 3.1. The Diurnal website informed patients, health professionals, investors and the general public about the company. Information on unlicensed medicines on the website related to general areas of proposed future therapeutic use (not specific indications) and clinical trial status and results only. There were no claims of efficacy or superiority. The webpage provided by the complainant featured a pipeline graphic designed to show health practitioners the areas of interest and progress in development for Diurnal in the field of endocrinology. This webpage might be referred to by the company in response to enquiries from health professionals about trials in disease areas as part of the company's legitimate scientific exchange. Diurnal submitted that the exchange of information was important to allow health professionals to discuss forthcoming trials and products with their patients in an informed way. The graphic was not promotional and so did not breach Clause 3.1.

Diurnal stated that it had not breached Clause 4.1 as relevant prescribing information had been provided where appropriate. The area of the website highlighted by the complainant was not promotional and so Clause 4.1 was not relevant. Where promotional information was available, the UK prescribing information was clearly displayed as 'one-click' link. Where information was provided specific to other nationality prescribers (ie Germany) the relevant prescribing information required by the relevant national code was provided.

Diurnal submitted that its website did not breach Clause 4.3 as the non-proprietary name had been provided where appropriate. The area of the website referred to by the complainant was not promotional and so Clause 4.3, which related to promotional material was not relevant. The names used for products in development were the development programmes names and would not be the eventual marketed name. However, Diurnal appreciated the feedback from the complainant in this case that inclusion of a non-propriety name would be helpful, and where possible it would add a relevant non-proprietary name. Where promotional information on the company's licensed product was available, the non-propriety name was provided adjacent to the most prominent display of the brand name.

Diurnal stated that although small and with only one licensed product, it had voluntarily complied with the Code since before applying for the market authorization for its first product. Diurnal regularly reviewed its activities and materials to ensure compliance with the Code and considered that high standards had been maintained in the development of the website. Diurnal denied a breach of Clause 9.1

As Diurnal did not consider that it had breached Clauses 3.1, 4.1, 4.3 or 9.1 in relation to its website it also did not consider that Clause 2 had been breached.

In summary, Diurnal did not consider that its website promoted unlicensed medicines and where there was promotional information, the correct information had been provided and high standards had been upheld.

PANEL RULING

In the Panel's view, it was not necessarily unacceptable for a company to refer in general terms to its pipeline products on its corporate website, however language, context, location, layout, intended audience and overall impression were important factors. Such references should not otherwise constitute promotion of an unlicensed medicine.

The Panel noted that the webpage at issue was in the health professionals' section of Diurnal's website. If health professionals wanted to find out about Diurnal medicines they had to visit the section of the website which detailed 'Products and Pipeline' – the two were not separate. The table of data which detailed Diurnal's European drug development pipeline, was within the 'Clinical Trials' section of 'Products and Pipeline'. Five products were listed in a table of data, although it was clear that one, Alkindi (hydrocortisone granules in capsules for opening) had been licensed for paediatric adrenal insufficiency in 2018. Four other products were listed (two with what appeared to be registered names) together with the indication for which they were being developed, their clinical trial status and the expected approval dates – variously 2021, 2023 and 'TBC' (to be confirmed).

The Panel noted from the downloaded page provided by Diurnal that the table of data was introduced by, *inter alia*, 'Diurnal is dedicated to bringing effective, high quality products to the

global market for the life-long treatment of chronic endocrine conditions.' In that regard, the Panel disagreed with Diurnal's submission that there were no claims for the products, in effect the company had implied that all medicines listed in the table were effective and high quality. In addition, the indications for all the medicines were stated. In the Panel's view, the webpage, which was directed at health professionals and was within a section of the website that promoted the company's licensed medicine, was promotional and designed to elicit interest in both Diurnal's licensed medicine and in its pipeline products. The Panel considered that the information about the unlicensed medicines constituted promotion of those medicines and a breach of Clause 3.1 was ruled.

The Panel further considered that the information provided about Alkindi within the table of data (product name and indication (paediatric adrenal insufficiency)) and on what, in the Panel's view was a promotional section of the website, was promotional. The Code required that in digital promotional material, the prescribing information as required by Clause 4.1 must be included in the material itself or by way of a clear and prominent direct single click link. There was no link to the Alkindi prescribing information on the webpage in question. A breach of Clause 4.1 was ruled. Further, the Panel noted that the non-proprietary name had not been provided. A breach of Clause 4.3 was ruled.

The Panel noted its rulings above and considered that high standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel considered that the response from Diurnal showed a poor understanding of the requirements of the Code. In the Panel's view the restrictions around how, when and what information could be provided about pipeline products and the definition of what constituted promotion of licensed medicines were such that companies should not combine the two. The promotion of a medicine prior to the grant of its marketing authorization was listed in the Code as an activity likely to be ruled in breach of Clause 2 – a sign of particular censure. The company had failed to recognise that the information it had provided was promotional. The Panel considered that the company's conduct in introducing, formatting and providing the information that it had, fell short of competent care; unlicensed medicines had been promoted to health professionals. A breach of Clause 2 was ruled.

Complaint received **24 October 2019**

Case completed **18 February 2020**