

**CASE AUTH/3357/5/20**

## **COMPLAINANT v COLONIS**

### **Alleged advertising of prescription-only medicines to the public**

**An anonymous complainant, who described him/herself as an independent healthcare digital consultant and writer, alleged that Colonis Pharma Limited advertised prescription-only medicines to the public on the products page of its corporate website.**

**The complainant submitted that displaying prescription-only medicines on a publicly accessible webpage was not in line with the Code. The content should have restricted access and only be viewable by health professionals that could prescribe the medicines.**

**The complainant noted that the products page of the company website allowed anyone from the general public to gain access to the prescription-only products that were being promoted online.**

**The detailed response from Colonis is given below.**

**The Panel noted Colonis' submission that the products webpage contained a list of products in its portfolio and for each product there was a photograph of the pack, the generic or brand name (as applicable), and the strength and dosage form were also listed. In addition, further information for each individual product was available by clicking on a product-related link on the webpage. This further information concerned (where applicable) the key indication(s), therapeutic area, formulation information, storage information, pack size, whether a dosage device was provided, batch size, stability data and site of manufacture. In addition, for each product, there were links to the SPC and package leaflet hosted on the eMC website.**

**The Panel noted Colonis' submission that its website was non-promotional and the information was provided as reference information for the public in accordance with the Code.**

**The Panel noted that there were no claims made for any of the products nor were the indications provided until a reader clicked on a specific product for further information. Whilst the Panel queried whether a prominent picture of the product in material for the public was appropriate, it did not consider that the complainant had discharged his/her burden of proof that the information provided on the products section of the Colonis website was such that it promoted prescription-only medicines to members of the public as alleged. No breaches of the Code were ruled including Clause 2.**

**An anonymous complainant, who described him/herself as an independent healthcare digital consultant and writer, alleged that Colonis Pharma Limited advertised prescription-only medicines to the general public on the products page of its corporate website.**

## COMPLAINT

The complainant stated that he/she worked in pharma marketing and submitted that displaying prescription-only medicines on a publicly accessible webpage was not in line with the Code. The content should have restricted access and only be viewable by health professionals that could prescribe the medicines.

The complainant stated that he/she came across the website whilst doing some commissioned research which involved analysing pharmaceutical websites. The complainant explained that one of the aspects of his/her research was about identifying how many websites did not conform to the regulations with regard to advertising prescription-only medicines; why that was; what typically happened when they were in breach and who policed that policy? The complainant stated that Colonis was one company he/she had found so far. The complainant noted that the products page of the company website allowed anyone from the general public to gain access to the prescription-only products that were being promoted online.

When writing to Colonis, the Authority asked it to consider the requirements of Clauses 9.1, 26.1, 28.1 and 2 of the Code.

## RESPONSE

Colonis stated that it was concerned to receive an allegation that the product pages on its website constituted advertising prescription-only medicines to the public. Colonis stated that it took its responsibility to comply with the Code extremely seriously. The company appreciated and respected the gravity of the complaint and it was company policy to uphold the Code in both letter and spirit. Colonis did not consider that it had breached the Code, nevertheless, it had temporarily removed the product pages from its website.

Colonis submitted that in addition to the clauses cited by the Authority, Clause 26.2 was also highly pertinent.

Colonis stated that its website content (colonis.co.uk) as at 1 June 2020 was last certified on 17 October 2019 (a copy of the relevant certificate and pdf of the content was provided). Colonis gave details of its signatories. The site was certified as a non-promotional item.

### Clauses 26.1 and 26.2

Colonis noted that Clause 26.1 provided that prescription-only medicines must not be advertised to the public. In that regard, Colonis stated that the first products webpage contained a list of products in the Colonis portfolio and for each product there was a photograph of the pack, the generic or brand name (as applicable), and the strength and dosage form were also listed. In addition, further information for each individual product was available by clicking on a product-related link on the first webpage. This further information concerned (where applicable) the key indication(s), therapeutic area, formulation information, storage information, pack size, whether a dosage device was provided, batch size, stability data and site of manufacture. In addition, for each product, there were links to the summary of product characteristics (SPC) and package leaflet (hosted on the Electronic Medicines Compendium (eMC) website which could only be accessed after the user clicked to acknowledge that he/she was leaving the Colonis website). There were also facilities allowing for adverse events to be reported and enquiries to be made.

Colonis did not consider that its product webpages advertised prescription-only medicines to the public; the information provided was allowed to be provided to the public in accordance with Clause 26.2, as the information was factual, presented in a balanced way, it did not raise unfounded hopes of successful treatment and was not misleading with respect to product safety. Furthermore, no statements were made that might have encouraged members of the public to ask their health professional to prescribe a specific prescription-only medicine.

Colonis further noted that the supplementary information to Clause 26.2 stated that Clause 26.2 allowed for the provision of non-promotional information about prescription-only medicines to the public as reference information made available by companies on their websites or otherwise as a resource for members of the public; and that any information so provided must observe the principles referred to above as set out in Clause 26.2. The supplementary information also stated that where reference information was provided, it was considered good practice to provide, as a minimum, the regulatory information comprising the SPC and the package leaflet, which Colonis had made available as explained above via a link to the eMC website (though public assessment reports were not included).

Colonis submitted that by providing links to the SPCs and package leaflets it had satisfied the provision in the supplementary information which stated that reference information must represent fairly the current body of evidence relating to a medicine and its benefit/risk profile. In addition, Colonis noted that no products claims were made.

Colonis did not consider that the Colonis website product pages were in breach of Clause 26.1.

#### Clause 28.1

Colonis noted that Clause 28.1 provided that promotional material about prescription-only medicines directed to a UK audience which was provided on the Internet must comply with all relevant requirements of the Code.

Colonis stated that as the product webpages in question were entirely in line with the requirements of Clause 26.1 and the material was not promotional, Clause 28.1 was not applicable.

#### Clause 9.1 and Clause 2

Colonis submitted that as there had been no breaches of the Code above, it followed that there had been no breach of Clause 9.1 (high standards must be maintained at all times) or Clause 2 (discredit to, and reduction in confidence in, the industry).

Colonis Pharma Limited and its parent, the Clinigen Group, advised that they would continue to comply with the ABPI Code in both letter and spirit, but would cease to be subject to the jurisdiction and oversight of the PMCPA once this complaint and Case AUTH/3358/6/20 had concluded.

### **PANEL RULING**

The Panel noted that the complainant was concerned that displaying prescription-only medicines on the publicly accessible product webpage of the Colonis corporate website

advertised prescription-only medicines to the general public. The products page, which appeared by clicking on the link provided by the complainant, was headed 'Our products currently licensed and available in the UK' followed by 'Our prescription-only products span a variety of therapeutic areas and are supplied to hospitals and pharmacies. We have an active product development team and a pipeline of products looking to meet the unmet clinical needs of patients in the UK'.

The Panel noted Colonis' submission that the products webpage contained a list of products in its portfolio and for each product there was a photograph of the pack, the generic or brand name (as applicable), and the strength and dosage form were also listed. In addition, further information for each individual product was available by clicking on a product-related link on the webpage. This further information concerned (where applicable) the key indication(s), therapeutic area, formulation information, storage information, pack size, whether a dosage device was provided, batch size, stability data and site of manufacture. In addition, for each product, there were links to the SPC and package leaflet hosted on the eMC website.

The Panel noted that Clause 26.1 prohibited the promotion of prescription-only medicines to the public. The Panel noted Colonis' submission that its website was non-promotional and the information was provided as reference information for the public in accordance with Clause 26.2.

The Panel noted that there were no claims made for any of the products nor were the indications provided until a reader clicked on a specific product for further information. Whilst the Panel queried whether a prominent picture of the product in material for the public was appropriate, it did not consider that the complainant had discharged his/her burden of proof that the information provided on the products section of the Colonis website was such that it promoted prescription-only medicines to members of the public as alleged. No breach of Clause 26.1 was ruled.

The Panel noted that Clause 28.1 stated that promotional material about prescription-only medicines directed to a UK audience, provided on the Internet, must comply with all the relevant requirements of the Code. The supplementary information to Clause 28.1 stated that unless access to promotional material about prescription-only medicines was limited to health professionals and other relevant decision makers, a pharmaceutical company website or a company sponsored website must provide information for the public as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified. This was to avoid the public needing to access material for health professionals unless they chose to.

The Panel noted its comments and ruling above and considered that as, in its view, the complainant had not discharged his/her burden of proof that the information provided on the products webpage of the Colonis website had promoted prescription-only medicines to members of the public, Clause 28.1 was not applicable and no breach of that clause was ruled.

The Panel noted its comments and rulings above and did not consider that there was evidence to show that Colonis had failed to maintain high standards in that regard and no breach of Clause 9.1 was ruled. The Panel consequently ruled no breach of Clause 2.

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During its consideration of this case, the Panel was concerned to note that, in addition to general information, a 'Get in touch' form was included on each product page for the reader to submit a query to the company.

The Panel considered that those who took the trouble to seek out a pharmaceutical company's website were likely to want to access as much information about medicines as possible. Whilst providing general contact details on company websites was good practice, the Panel considered that by providing a 'Get in touch' form on each product page and thus proactively inviting the public to contact the company for more information, Colonis was soliciting requests about specific prescription-only medicines and had thus gone beyond both the provision of a library resource and reactive information provided in response to a direct request (which, in the Panel's view, referred to an unsolicited request) as referred to in the supplementary information to Clause 26.2. In the Panel's view, however, the facility to get in touch with the company had not been the subject of the complaint and so no ruling was made in that regard.

**Complaint received      29 May 2020**

**Case completed          11 February 2021**