CASE/0255/08/24

COMPLAINANT v RECORDATI RARE DISEASES UK LTD

Allegations about a website

CASE SUMMARY

This complaint related to the 'Products' page of the health professional section of the Recordati Rare Diseases UK corporate website. The complainant alleged that the information within the webpage was promotional and therefore should have included prescribing information as required by the Code.

The outcome under the 2021 Code was:

Breach of Clause 12.1	**Failing to include up-to-date prescribing information**
Breach of Clause 5.1	**Failing to maintain high standards**

No Breach of Clause 2	**Requirement that activities or material must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

FULL CASE REPORT

A complaint about Recordati Rare Diseases UK Ltd was received from an anonymous, contactable complainant who described themselves as a health professional.

COMPLAINT

The complaint wording is reproduced below:

> "Dear PMCPA,
>
> At the website [link provided] there is a list of products with generic name, brand name, indication but there is no Prescribing Information for any of the products only a SmPC with no prices.
>
> Each of these products should have Prescribing Information available.
>
> [Screenshots provided]
>
> Please investigate"

When writing to Recordati Rare Diseases UK, the PMCPA asked it to consider the requirements of 12.1, 5.1 and 2 of the 2021 Code.

RECORDATI RARE DISEASES UK'S RESPONSE

The response from Recordati Rare Diseases UK is reproduced below:

> "Recordati Rare Diseases (RRD) is a member of ABPI and upholds high standards in adhering to the ABPI Code of Practice at all times. We take any complaints or allegations very seriously.
>
> In respect of the complaint, you ask us to respond in relation to the following Code clauses:
> *Clause 12.1*
> The prescribing information listed in Clause 12.2 must be provided in a clear and legible manner in all promotional material for a medicine except for abbreviated advertisements (see Clause 13). The prescribing information must be positioned for ease of reference and must not be presented in a manner such that the reader has to turn the material round in order to read it, for example, by providing it diagonally or around the page borders. The prescribing information must form part of the promotional material and must not be separate from it.
> *Clause 5.1*
> High standards must be maintained at all times.
> *Clause 2*
> Upholding Confidence in the Industry.
>
> RRD denies the complainant's allegations in relation to this matter.
>
> The website page outlined in the e-mail from the anonymous complainant is part of the RRD corporate website.
>
> The page in question ('Products page') is part of the HCP section of the website. The access to the 2 sections is from the [link provided] 'homepage'. This appears as first screen when accessing the site and the viewer is asked to confirm if they are a healthcare professional or not. If they click 'I am not a healthcare professional' this takes them to the public facing section of the corporate site (see the user journey). Once a HCP has confirmed their status they are able to access the Products page along with other relevant information. This includes Transparency and Joint Working Summaries which are also present on the public section of the site. The intended audience for this section of the website is stated at the top of the page *'The website is intended for healthcare professionals as a resource of UK and Irish company and product information'.*
>
> The Products page contains a factual list of RRD's UK product portfolio. Its purpose is to provide HCPs with access to regulatory product information. RRD has a wide range of diverse products across endocrinology, metabolic disorders, paediatric and oncology therapeutic areas. Not all products are likely to be of interest to every HCP. The page, therefore, of a simple table of brand name, generic name, indication and links to GB and NI SmPCs and PILs, helps the HCP access the relevant information. The indication is in

the SmPC and it has been added to the table to aid understanding of what each product is used for. Clause 1.17 states that communication is **not promotional** if it is factual, accurate, informative and does not include any product claims. We believe that this page is non-promotional as it links to regulatory documents and serves as a summary to help identify the relevant regulatory information for an HCP audience. Hence, we do not think prescribing information (PI) is required on this page.

A separate section 'Webinars' was added recently (June 2024) to the HCP section. It hosts a promotional webinar on Cystadrops and contains a link to appropriate PI.

The signatory for the HCP section of the site is a very experienced medical signatory ([sentence about experience of named signatory]). They have excellent, up-to-date knowledge of the Code and a good understanding of the issues at play with corporate and HCP websites.

After certification of the corporate website, a live test was conducted to check it was working correctly on laptop and mobile devices in line with good practice.

RRD is in the process of creating a bespoke HCP portal for our products. Although we do not consider the HCP Product page to be in breach of the Code, we have decided to revert the corporate site to be public facing only and have removed the HCP sections until a full update can be made.

We believe our actions in developing and approving this page demonstrate that we have maintained high standards in line with the requirements of Clause 5.1. We do not consider that our actions could be considered to bring discredit upon, or reduce confidence in, the pharmaceutical industry in breach of Clause 2.

In summary we do not consider that we have breached Clauses, 12.1, 5.1 or 2 of the ABPI Code of Practice 2021. We believe that we have demonstrated a robust decision making and approval process in relation to the material in question.

I have attached the information requested. Please do not hesitate to get in touch if you require any further information."

PANEL RULING

This complaint related to the 'Products' page of the health professional section of the Recordati Rare Diseases UK corporate website. The complainant alleged that the information within the webpage was promotional and therefore should have included prescribing information as required by the Code.

The 'Products' page of the Recordati Rare Disease UK corporate website

Upon accessing the Recordati Rare Disease UK corporate website, visitors were prompted to confirm if they were a health professional. If they clicked '*I am not a healthcare professiona*l', they were directed to the public facing section of the corporate website. Alternatively, if they clicked '*I confirm that I am a healthcare professional'*, they were then able to access the website intended for health professionals, which included the 'Products' page, which was the subject of this complaint.

The 'Products' page featured a navigation banner at the top, with the statement *'This website is intended for healthcare professionals as a resource of UK and Ireland company and product information'*. Directly below the banner was a statement on how to report adverse events. The remainder of the webpage contained a table of the Recordati Rare Diseases UK medicines with marketing authorisations in the UK. The table included the:

- product brand name,
- generic name,
- licenced indication as per the summary of product characteristics (SPC),
- medicine's pharmaceutical form, and
- links to the product SPC and patient information leaflet for both Great Britain and Northern Ireland where available.

Allegation regarding missing prescribing information (Clause 12.1)

Clause 12.1 of the Code stated: *'the prescribing information listed in Clause 12.2 must be provided in a clear and legible manner in all promotional material for a medicine except for abbreviated advertisements*. In the Panel's view, the requirement for the 'Products' page to provide prescribing information was dependent on whether the information within that page was promotional, as defined by Clause 1.17.

The Panel noted Recordati Rare Diseases UK's submission that:

1. Clause 1.17 stated that *'communication is non-promotional if it is factual, accurate, informative and does include any product claims'*, and

2. the information on the 'Products' page was factual and intended to provide health professionals with access to regulatory product information.

During its deliberation, the Panel noted that the bullet-point of Clause 1.17 that Recordati Rare Disease UK was quoting from, included examples of where it would apply i.e. information relating to *'pack changes, adverse reaction warnings, trade catalogues and price lists provided they include no product claims'*. The Panel's view was that none of those examples applied here.

The Panel considered that the information within the 'Products' page was *not* exempt from the definition of promotion because it included the brand and generic name of the medicine, alongside the licenced indication and pharmaceutical form. Given the broad definition of promotion, the Panel concluded that the 'Products' page was therefore promotional and should have included prescribing information for the medicines listed. The Panel ruled a **breach of Clause 12.1.**

Failure to maintain high standards (Clause 5.1)

In its assessment of whether there had been a breach of Clause 5.1, the Panel took into consideration Recordati Rare Disease UK's submission that the 'Products' page formed part of its corporate website. The Panel also acknowledged that the page was not part of a promotional campaign, it did contain links to the SPCs for all products, and that many of the elements that constitute prescribing information were available either on the page itself or via a direct, single click link.

However, the breach of Clause 12.1 resulted from Recordati Rare Disease UK's failure to identify that the contents of the 'Products' page was promotional and, in the Panel's view, that was an error that was sufficiently serious to suggest that high standards had not been maintained. The Panel also took account of the fact that two of the medicines featured on the 'Products' were black triangle medicines. The Panel considered that greater care should have been taken to ensure that information made available about medicines that were subject to additional monitoring met the requirements of the Code. Based on these factors combined, the Panel concluded that high standards had not been maintained and ruled a **breach of Clause 5.1.**

Clause 2

The Panel noted that Clause 2 was a sign of particular censure and was reserved for such use. In the Panel's opinion the breaches of Clause 12.1 and 5.1 were proportionate and adequately covered the complaint. The Panel ruled **no breach of Clause 2.**

Complaint received **01 August 2024**

Case completed **26 August 2025**