

**CASE AUTH/3797/7/23**

## **COMPLAINANT v BESINS HEALTHCARE**

**Alleged disguised promotion on a website**

### **CASE SUMMARY**

**This case was in relation to three webpages on the Besins Hormone Academy website. The complainant alleged that the promotional nature of the webpages was disguised.**

**The outcome under the 2021 Code was:**

<b>No Breach of Clause 5.1</b>	<b>Requirement to maintain high standards at all times</b>
<b>No Breach of Clause 15.6</b>	<b>Requirement that promotional material and activities must not be disguised</b>

**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 Besins Healthcare (UK) Ltd was received from a complainant who described themselves as a concerned health professional.

#### **COMPLAINT**

The complaint wording is reproduced below:

“The following website is apparently a promotional website [URL and screenshot provided] – although there is nothing on the website that explicitly states this is the case.

On the web page [URL and screenshot provided] of the ‘Our Programmes’ webpage]

The Menopause roadshow [screenshot provided] is the first time there is an oblique mention that this is in fact all a promotional website – with a link to the Prescribing Information present.

All web pages appear to have the same adverse events statement (as shown below [screenshot provided]) which would again indicate that this has been thought to be a promotional website.”

When writing to Besins, the PMCPA asked it to consider the requirements of Clauses 5.1 and 5.6 of the 2021 Code. Besins responded to the allegations, including consideration of the requirements of Clause 15.6 (see response from Besins below). The case preparation manager

wrote again to Besins following receipt of its response to inform them that Clause 5.6 had been incorrectly cited, instead of Clause 15.6, and to ask whether they had any further comments in relation to Clause 15.6. Besins confirmed that it had no further comments and they were happy for the complaint to be dealt with under Clause 15.6 instead of Clause 5.6.

## **BESIN'S RESPONSE**

The response from Besins is reproduced below:

“At Besins Healthcare (UK) Ltd we take compliance with the Code extremely seriously and have in place standards and processes to help ensure such compliance.

We have therefore suspended the website whilst this matter is investigated and resolved. In the below we have responded to the concerns raised by the complainant in full and have attached the requested information as enclosures as well as a password protected link to the website in a test environment that is not externally accessible.

**Allegation from complainant** – that the Besins Hormone Academy website “...is apparently a promotional website ... although there is nothing on the website that explicitly states this is the case.”

The complainant has referred to the ‘Besins Hormone Academy’ website and appears to consider it to be disguised promotion in nature (although they don’t use precisely those terms), specifically because of the following which we will address in turn as well as in relation to clauses 5.1 & 5.6 as requested in your letter:

- That there is no explicit reference to ‘promotion’ on the website;
- That there is inclusion of a link to prescribing information
- That there is inclusion of an adverse event reporting statement

The website itself is intended for healthcare professionals only and is clearly sign-posted as such when directly accessed, with the following clear statement:

“This site has been developed by Besins Healthcare Ltd and is for Healthcare Professionals Only. To proceed, please select from the below – [users are then required to select] – I am a UK healthcare professional [or] I am a member of the public”

Those selecting HCP status are taken to the Besins Hormone Academy website whilst those selecting member of the public status are taken to links for separate disease awareness/educational websites designed for a general public audience searching for information related to menopause or testosterone deficiency created by Besins Healthcare (UK) Ltd or independent 3<sup>rd</sup> parties.

Furthermore, the top of every page of the Besins Hormone Academy website has the following clear and prominent declaration of the intended audience for the website:

“This site has been created by Besins Healthcare for UK healthcare professionals only”

The website is intended to host high quality information on disease areas (diagnosis, investigation, pathology etc.) as well as treatments in women's and men's health for which Besins Healthcare (UK) Ltd market prescription medicines. As such, the website has an overall promotional intent and all of the 'job bags' relating to it are categorized as promotional and contain details of intended audience and methods of distribution that are appropriate for promotion and were certified accordingly. Please note that, in practice, a multi-page website such as this will have individual pages which do not have any promotional content in and of themselves. The most obvious example of this would be the 'Contact' page which only contains information on various means to contact the company, however as a single, self-contained entity, the website as a whole has a promotional intent, was categorized and approved as promotion, and meets the Code requirements for promotion through (amongst other things) the provision of prescribing information and an adverse events reporting statement. Please note that the job bag for the webpage intended for those who click on 'I am a member of the public' was categorized as promotional only because the website as a whole is promotional and not because the page itself has any promotional content or intent (which it does not).

This website has not (in and of itself) been externally promoted nor has it been 'search engine optimised' to be easily discoverable. It does not come up early in internet searches unless the exact search terms such as 'Besins Hormone Academy' are used. Instead, HCPs were directed to it by means of invitations which are described in detail below. It is unlikely that HCPs would have stumbled across this website by accident, independently of these invitations. However, for HCPs coming across it via a Google search or similar, it would be very clear that it is a pharmaceutical company website relating to particular disease areas intended for HCPs and therefore that any pages containing links to prescribing information and adverse event statement are likely to have a promotional intent. Therefore the promotion was not disguised in nature or intent.

The website was launched on April 27<sup>th</sup>, principally for the initial purpose of hosting registration of invited HCPs for the 'Menopause Roadshow' promotional meetings organised and funded by Besins Healthcare (UK) Ltd and it currently contains relatively little content other than that relating to these 'Roadshows'. Five of these meetings have been held in the period June to July 2023 and were categorised as promotional by Besins Healthcare (UK) Ltd because (although highly educational in nature, extensively covering disease definition, diagnosis, pathophysiology and investigation), they included substantive sections on treatment options with prescription medicines, including those of Besins Healthcare (UK) Ltd. The agendas and content of all five meetings were identical and only differed in location. The fact that these were of a promotional nature (as well as being educational in nature) was made clear at the outset in the email invitations that were sent to selected HCPs (example enclosed). The emails were created and certified by Besins Healthcare (UK) Ltd and sent by a 3<sup>rd</sup> party to HCPs that had provided consent for receipt of promotional emails. Specifically, the following statement was included prominently at the outset of the invitation emails:

*"This email has been sent by [named publication] and contains third party promotional information. This is a Besins Healthcare educational programme and is for UK Healthcare professionals only. Besins Healthcare medicines will be discussed."*

These invitation emails also included an adverse event reporting statement and link to prescribing information of relevant products in HRT (Oestrogel, Utrogestan and Imvaggis). Those HCPs who wished to register for any of these meetings could click a link to the Besins Hormone Academy website 'Events' page and where they could choose amongst the event locations for a 'Menopause Roadshow' meeting and register for attendance.

These emails were distributed mainly to a primary care audience comprising of GPs, nurses and pharmacists because menopause related symptoms are likely to be a common presentation in primary care and so the interest of this audience in this subject matter can be reasonably assumed.

The distribution of these emails was undertaken on behalf of Besins Healthcare (UK) Ltd by the following external electronic journals to their respective subscribers – [four named publications] – for whom relevant consents were in place.

Invitations to the Roadshows were also posted as promotional banner adverts in HCP journals, with customary prescribing information and adverse event statement in the manner familiar to promotional banner adverts and with the following declaration statement common to them all (example from [named publication] enclosed):

"This programme is organized and funded by Besins Healthcare (UK) Ltd and intended for UK healthcare professionals only. Product information will be shared."

The Besins Healthcare (UK) Ltd sales force also distributed invitation emails to HCPs for whom the company has a documented record of consent or to those HCPs that had specifically requested it. These emails had the following declarations in the subject line:

"You're invite to attend the Besins Menopause Educational Roadshow 2023 (Besins promotional event)"

Furthermore, invitations were also posted via the LinkedIn account of [named agency] (the medical educational agency working for and on behalf of Besins Healthcare (UK) Ltd as a paid-for 'InMail' posting directed at LinkedIn users who had been specifically identified as (broad categories of) HCPs and contained the following prominent declaration at the outset:

"This is a Besins Healthcare educational promotional programme and is for UK Healthcare professionals only. Besins Healthcare medicines will be discussed."

The content of the Roadshow meetings was identical across the 5 locations around the UK where it was hosted, and comprised of an introductory level of education on Menopause and its management.

The symptoms of menopause are extremely prevalent and are an increasingly frequent reason for patients to present (with a variety of symptoms) to HCPs in primary and secondary care. The topic has a high profile in the public and medical media and therefore it was reasonable to assume that the (broad) categories of HCPs invited to the 'Roadshow' meetings (and therefore directed to the website) would have an interest in it.

Given the nature of the meetings content and the broad relevance of menopause symptoms to HCPs, it was reasonable to assume the interest and relevance of the meeting content in those to whom the invitations were sent. The promotional intent of this website and the audience and methods of distribution that are appropriate for such promotion were detailed in the certified job bags relating to the website, reflecting the robust standards that Besins Healthcare (UK) Ltd has in place for the control and compliance of such activities. **Therefore, Besins Healthcare (UK) Ltd do not consider that there was a breach of Clause 5.6 and nor that there was a breach of Clause 5.1**

We now address the points raised by the complainant in turn:

- That there is no explicit reference to 'promotion' on the website;

There is no mandatory requirement in the Code for promotional material to carry an explicit statement to that effect as long as the material otherwise meets the requirements of promotional material including Prescribing Information and adverse event reporting statement. As explained above, the Menopause Roadshow meetings were categorised as promotional and so the corresponding sections of the website relating to these meetings included a one-click link to the prescribing information for relevant products (Oestrogel, Utrogestan & Imvaggis) as well as an adverse event reporting statement. These sections contained references to classes of treatment but not specific products.

As explained above, the website itself was not advertised in any way and those being directed to it by Besins Healthcare (UK) Ltd were only those HCPs who had been emailed an invitation to the Roadshows or clicked on banner adverts, or clicked on a LinkedIn post, all of which had explicit statements at the outset as to the nature of what the HCP was clicking on and into.

It is unlikely that HCPs would have stumbled across this website by accident, independently of the 'Roadshow' meetings invitations that had been sent out. However, for HCPs coming across it via a Google search or similar, it would be very clear that it is a pharmaceutical company website relating to particular disease areas intended for HCPs and therefore that any pages containing links to prescribing information and adverse event statement are likely to have a promotional intent. Therefore the promotion was not disguised in nature or intent

- That there is inclusion of a link to prescribing information;

As explained above, the Roadshows were categorised as promotional and so Prescribing Information links for relevant products were applied to the specific pages on the website that referred to these meetings. It would be apparent to an HCP that an explicitly company website relating to particular disease areas and with Prescribing Information (and adverse event reporting statement) is likely to have a promotional intent. Therefore the promotion was not disguised in nature or intent

- That there is inclusion of an adverse event reporting statement

As explained above, the website had an overall promotional intent and the corresponding job bags were categorised as promotional and so adverse event reporting statements were applied to all pages on the website. It would be apparent to an HCP that an explicitly company website relating to particular disease areas and with an adverse event reporting statement (as well as Prescribing Information) is likely to have a promotional intent. Therefore the promotion was not disguised in nature or intent

### **Description of all sections of the website**

#### The 'Home' page

This is intended to set out the over-arching high quality informational purposes of the website and does not contain any product promotional claims.

#### The 'Our Programmes' page

The first page contains a reference to 'Testosterone Deficiency' but no link or related content at present. However, there is a link to 'Menopause' which leads to pages containing the agenda and location/date details for the 5 'Menopause Roadshow' meetings and all of the pages of this part of the website contained one-click link to Prescribing Information for the relevant products and an Adverse Event reporting statement appeared at the bottom. This section of the website has the following sub-sections:

- 'Overview' page – this has a brief description of the 'Roadshow' meetings and no product information or claims.
- 'Events' page – this contained links to each of the five 'Roadshow' meetings and does not contain any product related information or claims.
- Five separate pages, each with logistical details for the dates and venues available for the five 'Roadshow' meetings. These did not contain any product-related information or claims.
- 'Agenda' page – a single page setting out the common agenda for each of the five 'Roadshow' meetings. This had some reference to classes of medicine but not specific product related information or claims.
- 'On-demand resources' – this page currently has no material and will be updated in future.
- 'Prescribing Information' page – contains a one-click link to the abbreviated prescribing information for three products – Oestrogel, Utrogestan and Imvaggis
- Registration page for the 'Roadshow' meetings, including a post meeting feedback survey. This page has no product information or claims and has now expired since the meetings are over.

The website had not been promoted or advertised to HCPs and was not 'search engine optimised' and so any HCPs viewing these pages would almost certainly have arrived there via the promotional emails sent to them or a banner advert they clicked on, or a

LinkedIn post they followed as described above. Also as described, the agendas were treated as promotional because the content of the meetings themselves (although comprehensively education in nature) was categorised as promotional and so all the pages in this section contain a single-click link to Prescribing Information and adverse event reporting statement.

Those HCPs who had been sent an email with a link to this website or who saw a banner advert or who saw a LinkedIn post would have seen a prominent statement at the outset as described previously and from which it would have been reasonably clear to HCPs that they were clicking on (or into) promotional material.

Furthermore, for the few (if any) HCPs coming across this website independently of the invitation emails/posts, it would be apparent that an explicitly company website such as this relating to particular disease areas and with Prescribing Information (and adverse event reporting statement) is likely to have a promotional intent. Therefore, the promotion was not disguised in nature or intent

#### The 'About' page

This page is focused mainly on brief descriptions of Besins Healthcare, its history and purposes and is intended to be no more than corporate promotional, including with a link to the Besins Healthcare (UK) Ltd corporate website for the UK. Accordingly, it has no product promotional statements or intent.

#### The 'Contact us' page

As implied by the title of this page, this is a standard section with details for various means of contacting Besins Healthcare (UK) Ltd as well as [named agency] which is the external agency organizing the 'Menopause Roadshow' meetings for and on behalf of Besins Healthcare (UK) Ltd. There is no promotional content or intent for this page.

#### The 'FAQ' section

This is for those proactively searching for answers to specific questions and has no product promotional claims. It currently contains 5 'Q&As' as follows:

- A list of all Besins Healthcare (UK) Ltd products with external links to the Electronic Medicines Compendium for those searching for information about Besins Healthcare (UK) Ltd products and has no product promotional claims or therapy area information.
- Details for contacting a Besins Healthcare (UK) Ltd representative.
- Consent section for receiving emails from Besins Healthcare (UK) Ltd (this would be of use in the future once the website has been fully built and search engine optimized so that HCPs coming across this site may have need for this consenting section)
- Information on supply status of Besins Healthcare (UK) Ltd products – this contains a link to the separate Besins Healthcare (UK) Ltd (non-promotional) corporate website, supply status section which has succinct factual information on which products have supply issues and which do not.

- A help section for those having trouble registering for the Menopause Roadshow meetings and which contains no product promotional information.

Please note that if clicking a link takes a user away from the Besins Hormone Academy website, there is a 'pop-up' message to that effect.

## SUMMARY

The 'Besins Hormone Academy' website is a promotional website that was placed on the internet for the initial purpose of facilitating the registration of HCPs to the promotional 'Menopause Roadshow' meetings. These meetings were advertised via emails, banner adverts or LinkedIn post that contained a link to the website. Those invitations had prominent declarations as to their nature at the outset and it would have been clear to an HCP engaging with them that they were clicking on (or into) promotional content.

The website has not been search-engine optimized and so is difficult to find without already knowing of its presence. However, for any HCPs that came across this website independently of the 'Roadshow' invitations (for example through a Google search), it would be apparent that an explicitly pharmaceutical company website for HCPs such as this (with statements on it at the outset to that effect) relating to particular disease areas and with Prescribing Information (and adverse event reporting statement) is likely to have a promotional intent. Therefore Besins Healthcare (UK) Ltd do not consider that this promotion was disguised in nature or intent, nor that there was a breach of Clause 15.6

The symptoms of menopause are extremely prevalent and are an increasingly frequent reason for patients to present (with a variety of symptoms) to HCPs in primary and secondary care. The topic has a high profile in the public and medical media and therefore it was reasonable to assume that the (broad) categories of HCPs invited to the 'Roadshow' meetings (and therefore directed to the website) would have an interest in it. Therefore, Besins Healthcare (UK) Ltd do not consider that there was a breach of Clause 5.6.

Given the detailed position set out above Besins Healthcare (UK) Ltd do not consider the website was in breach of Clause 15.6 or 5.6, and given the controls documented in the certified 'job bags' which helped ensure such compliance, Besins Healthcare (UK) Ltd do not consider that there was a breach of Clause 5.1."

## PANEL RULING

### The complaint

The Constitution and Procedure states that the complainant has the burden of proving their complaint on the balance of probabilities. All complaints are judged by the Panel on the evidence provided by the parties.

Following the clarification of the correct clause numbers by the case preparation manager, the Panel considered the complainant's allegations under the following clauses of the 2021 Code:

1. Clause 5.1 (high standards must be maintained at all times)
2. Clause 15.6 (Promotional material and activities must not be disguised)

The Panel noted that the website that was the subject of the complaint had a landing page that asked users to confirm if they were a member of the public or a healthcare professional (“HCP”). Only those stating they were an HCP were then taken to the webpages that were the subject of this complaint.

The complainant referred the Panel to three webpages (the homepage, the “Our programmes” page, and a “Welcome to the Menopause Roadshow 2023” page). The Panel noted that each webpage had a banner at the top stating “This site has been created by Besins Healthcare for UK healthcare professionals only”. Below this was the navigation bar, with a Besins logo and the words “The Besins Hormone Academy”. The page footers included, among other things, a box with the adverse events reporting statement.

The first webpage referred to by the complainant was titled “Welcome to the Besins Hormone Academy”. Below that title, there was a statement reading:

*“Welcome to the Besins Hormone Academy. This Academy will house essential learning materials and key resources to support your continued professional development in the areas of women’s and men’s health.”*

Beneath this, in a blue highlight box with an image, was a link to another webpage, accompanied by the text:

*“What is happening in 2023? We are pleased to announce a brand new medical education programme. The Menopause Roadshow 2023 will cover fundamental topics, including diagnosis, holistic treatment, and communication. We are holding five fantastic interactive events across the UK this June and July.”*

Below this, a vision statement and mission statement were presented. The mission statement was:

*“To support and equip clinicians with evidence-based education and tools on balanced holistic treatment, including hormone replacement therapies (HRT).”*

The second webpage referred to by the complainant was titled “Our programmes”. It had, among other things, a link to “Learn more” presented in a coloured box titled “Menopause”, with an image of a woman and the text:

*“Do you speak menopause? Helping you make confident diagnoses and treatment decisions at one of our live, free-to-attend educational events across the UK.”*

The Panel noted Besins’ submission in this regard that the link in this ‘Menopause’ box led to pages containing the agenda and location/date details for five ‘Menopause Roadshow’ meetings.

The third webpage referred to by the complainant was titled “Welcome to the Menopause Roadshow 2023”. It provided a broad overview about the menopause roadshow and links to

further information and resources. The navigation bar at the top of the page included a link to the prescribing information.

**Clause 15.6 – promotional material and activities must not be disguised**

The Panel noted the complainant's allegation that "The following website is apparently a promotional website – although there is nothing on the website that explicitly states this is the case." and that "the Menopause Roadshow [webpage was] the first time there [was] an oblique mention" that this was a promotional website, with a link to prescribing information present, and "all webpages appear to have the same adverse events statement ... which would again indicate that this has been thought to be a promotional website".

While some of the complaint wording was unclear, the Panel understood that there was primarily an allegation of disguised promotion, as the website at issue was "promotional" but "there [was] nothing on the website that explicitly states this is the case". The Panel understood that the references within the complaint to the presence of prescribing information and the adverse event reporting statement related to the complainant demonstrating that the website was promotional, rather than constituting an allegation in themselves. It was not for the Panel to make out a complainant's case for them or to infer detailed reasons to support the allegation(s) on their behalf.

The Code did not require promotional material to be labelled as such, provided it was not disguised.

The Panel noted that all three webpages at issue included the Besins logo alongside the words "The Besins Hormone Academy". The Panel considered that it would be sufficiently clear to health professionals who accessed the webpages that "The Besins Hormone Academy" was a Besins website and that it was likely to include promotional information about Besins' hormone products.

The Panel considered that the presence of a link to the prescribing information on the "Welcome to the Menopause Roadshow 2023" webpage, and the adverse event reporting statement on the footer of each webpage at issue would provide another indicator to the reader that the webpages could contain promotional content.

The Panel noted Besins' submission that the webpages at issue were not, in and of themselves, actively promoted online and nor were they search engine optimised so as to be easily discoverable. The Panel considered that, on the balance of probabilities, HCPs would have been made aware of these webpages via targeted emails, promotional banner advertisements in health professional journals or LinkedIn 'InMail' posts in which it was made clear that the Menopause Roadshow meetings were promotional. In this regard, the Panel noted that the email invitations, as submitted by Besins, stated at the top:

*"This is a Besins Healthcare UK Ltd educational programme and is for UK Healthcare professionals only. Besins Healthcare medicines will be discussed."*

The Panel noted from Besins' submission that similar declarations were made on the promotional banner advertisements and the LinkedIn 'InMail' posts.

Noting the above, the Panel considered that the complainant had not established, on the balance of probabilities, that the promotional nature of the website was disguised. The Panel therefore ruled **no breach of Clause 15.6**.

**Clause 5.1 – high standards must be maintained at all times**

Noting its comments and ruling of no breach of the Code above, the Panel did not consider that the complainant had established that Besins Healthcare Ltd had failed to maintain high standards. The Panel ruled **no breach of Clause 5.1**.

**Complaint received      6 July 2023**

**Case completed          16 September 2024**