CASE/0722/09/25

COMPLAINANT v IBSA PHARMA

Allegations about company websites promoting to the public

CASE SUMMARY

This case was in relation to two websites from IBSA Pharma: the IBSA UK corporate website and the IBSA UK fertility website. The complainant alleged that the corporate website was not split between information for health professionals and that for the general public and patients on treatment. Citing specific webpages from the two websites, the complainant alleged that the availability of certain information to the general public constituted promotion of prescription only medicines to the public. The complainant further alleged that, on one of the webpages, the black triangles present were not the correct colour.

The outcome under the 2024 Code was:

Breach of Clause 5.1 (x2)	**Failing to maintain high standards**
Breach of Clause 26.1	**Advertising a prescription only medicine to the public**

No Breach of Clause 5.1	**Requirement for companies to maintain high standards at all times**
No Breach of Clause 6.1	**Requirement that information/claims/comparisons must not be misleading**
No Breach of Clause 12.7	**Requirement to include the black triangle in promotional material**
No Breach of Clause 26.1 (x2)	**Requirement to not advertise prescription only medicines to the public**

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 IBSA Pharma UK was received from a contactable complainant who described themselves as a health professional.

COMPLAINT

The complaint wording is reproduced below:

> "The following website [URL provided] describes both the company, and also has a tab named "Products" (alongside therapy areas). The website doesn't appear to be split

between what is for healthcare professionals / the general public and patients on treatment.

On the link [URL provided], the following information is available for all – not just healthcare professionals but also the general public and patients.

The black triangles present are not even the correct colour – they are not black.

For Silandyl (Sildenafil), there is a link to the SmPC [summary of product characteristics] but no link to Prescribing information so I am unclear whether this is aimed at Healthcare professionals or whether SmPCs (rather than PILs [patient information leaflets]) are being offered to the general public.

The link for Fertility is to another website owned by the company [URL provided] – which seems to be aimed to the general public. But this isn't about the disease area, again is mentioning products, has links to SmPCs and even has a safety statement for patients on treatment. Again, this is promoting to the general public by displaying material that should be only for patients on treatment.

The tab for patients ([URL provided]) who have been prescribed displays not just the product they have been prescribed, but others that they might not have – so again is promoting to the general public.

This disjointed state of affairs on linked website displays a lack of understanding of what is appropriate – please investigate."

When writing to IBSA, the PMCPA asked it to consider the requirements of Clauses 5.1, 6.1, 12.10 (later corrected to 12.7) and 26.1 of the 2024 Code.

IBSA'S RESPONSE

The response from IBSA is reproduced below:

"Thank you for your letter dated 16 September 2025 regarding the above case.

IBSA UK appreciates and respects the gravity of this complaint. It is our firm policy to uphold the ABPI Code of Practice in both letter and spirit, and we are committed to taking all necessary steps to maintain the highest standards of compliance and patient safety.

You have asked us to consider Clauses 5.1, 6.1, 12.10 and 26.1 of the ABPI 2024 Code. We address the issues raised in the order set out by the complainant.

We are attaching the certificates of approval for the website content (with signatory qualifications), and other supporting documentation. The corporate and fertility websites were certified in advance in accordance with Clause 8.1 of the Code. The certification was completed by [named signatory and signatory qualifications], IBSA consultant final signatory. Details of the certification can be found below, and copies of the certificates are enclosed.

Site Name	Job Bag Code	Date of certification
IBSA UK – Corporate Homepage	UKCOR00953	8th August 2025
IBSA UK – Fertility	UKCOR00943	23rd July 2025

1. General corporate website ([URL provided])

The complainant raises concerns about the presence of 'Therapy Areas' and 'Products' sections, questioning the lack of visible distinction between content for healthcare professionals, members of the public, and patients on treatment.

The primary purpose of the corporate site is to provide factual, non-promotional information concerning IBSA UK as a company and its therapeutic portfolio. All content on the IBSA UK corporate website is provided as reference material for the general public, in accordance with Clause 26.2 of the ABPI Code of Practice.

Within the 'Products' section, only brand names, generic names and pharmaceutical formulations are listed, accompanied by links to SmPCs where applicable. At no point are efficacy claims, comparative statements, or promotional straplines included.

All information made public on the corporate site is strictly factual and compliant with the definition of reference material set out in Clause 26.2 supplementary information. Therefore, the creation of entirely separate sections for different audiences is unnecessary for this category of content. The material is suitable for all audiences and does not include content intended solely for healthcare professionals or patients already prescribed treatment. This approach is aligned with the supplementary guidance to Clause 26.2, which sets out that factual, non-promotional reference information can be made available to the general public.

Accordingly, we respectfully submit that the website does not constitute promotion to the public as alleged, and thus, there has been no breach of Clause 26.1.

2. Products page ([URL provided])

Accessibility to all audiences
The complainant notes that the 'Products' page is accessible to all audiences, including members of the public.

The content of this page is strictly limited to the names of products, their pharmaceutical forms, and links to the relevant Summaries of Product Characteristics (SmPCs). No statements are made regarding efficacy, no comparative claims are present, and no promotional straplines or language appear in this section.

This 'Products' page design and content are fully aligned with Clause 26.2 of the ABPI Code of Practice. This clause and its supplementary information permit companies to provide factual, balanced and non-promotional reference information about medicines for public access. By limiting the 'Products' page to this reference information and

signposting viewers to the official Summary of Product Characteristics (SmPCs) for more details, the site meets both the spirit and the letter of the Code.

Reference information is intended to inform, not to promote, and in this context, separate access restrictions or audience segregation are not mandated by the ABPI Code.

Provision of this information, in the absence of promotional content, is specifically supported and encouraged under Clause 26.2.

Accordingly, the page does not constitute promotion to the public as alleged by the complainant, and no breach of Clause 26.1 has occurred.

2.1 Black triangles

Upon review, it was determined that this was the result of a technical error by a third-party provider, which led to the use of a deep navy triangle rather than black. This error was isolated and rectified immediately upon discovery, and a corrective and preventative action (CAPA) process was initiated to prevent recurrence.

We regret this oversight and wish to assure the Authority that both corrective and preventive measures were implemented promptly. The CAPA is designed to strengthen ongoing compliance, including supplier checks and validation protocols for future updates.

This incident does not reflect a failure in IBSA UK's overall approach to compliance with Clause 12.7 of the ABPI 2024 Code, as all practical steps were taken to address and prevent similar errors. It is submitted that this was an isolated occurrence, not indicative of systemic failure.

It is noted that reference to Clause 12.10 in the complaint appears to be in error, as Clause 12.10 does not exist in the current 2024 ABPI Code.

2.2 Silandyl (Sildenafil ODF) – prescribing information

The complainant queried why the Silandyl section on the 'Products' page provides a link to the SmPC but not prescribing information.

Prescribing information is only required for promotional material, not for factual, non-promotional content. The 'Urogynaecology' section of the 'Products' page, that lists Silandyl, serves, as a corporate, public-facing reference library, and is intended to present factual information in accordance with Clause 26.2 of the ABPI Code of Practice.

Including the SmPC is recognised as good practice for reference material and is entirely consistent with Clause 26.2 and its supplementary information, which explicitly permits the provision of SmPCs and other factual documents as reference material for patients and the general public. Since the page is neither promotional nor aimed at healthcare professionals specifically, inclusion of prescribing information is not necessary or appropriate.

This ensures transparent, non-promotional communication, and aligns with best practice for public-facing reference webpages.

3. Fertility website – public section ([URL provided])

The complainant suggests this section is aimed at the public but mentions products, includes links to SmPCs, and contains a patient safety statement.

The public section of our fertility website is clearly segmented, with separate navigation for Health Care Professionals (HCPs), patients, and members of the public, in line with PMCPA guidance for the separation and identification of content intended for different audiences. This ensures that information provided to the public is factual, non-promotional, and presented appropriately per Clause 26.2 of the ABPI Code of Practice.

Within the members of the public section, product names are listed and links to SmPCs are provided as reference material, entirely consistent with Clause 26.2 and related supplementary information outlined in the Code. No claims of efficacy, comparative statements, or promotional content appear in this section.

The patient safety statement is included solely to highlight important safety considerations and encourage appropriate reporting of side effects; it does not constitute product promotion. Its presence ensures transparency and supports informed decision-making by the public.

We respectfully submit that the statement and the provision of links to SmPCs, provide factual, non-promotional information and does not constitute product promotion, consistent with the ABPI Code.

4. Fertility website – patient section ([URL provided])

The complainant suggests that patients can view information on products they may not have been prescribed, which is described as promotion to the 'general public'.

It should be noted that the screenshot provided in the complaint does not correspond to the actual landing page to which the 'Patients' link directs.

The live patient section landing page is controlled by a clear self-validation process that requires users to confirm their patient status.

Only after a visitor has confirmed their patient status will they see the page clearly headed 'Prescribed an IBSA medicine?' which explicitly addresses only patients who have already been prescribed an IBSA product. The accompanying text makes clear that the section is designed to support the correct use of treatment already prescribed, by providing factual, practical information. Only after this step visitors can access the patient information area. Those who select 'not a patient' are directed to the public section, ensuring segmentation consistent with Clause 26.2 and PMCPA guidance for digital communications.

Within the patient section, information is explicitly tailored for those prescribed an IBSA medicine. The text on each page is limited to the licensed indication and practical information to facilitate safe, correct medicine use.

Prior to receiving the complaint, the patient section displayed each product entry as a short overview (licensed indication only) and a pack shot, provided exclusively to enhance correct use and minimize medication errors in complex fertility regimens—an approach consistent with past rulings, including AUTH/3329/3/20 and AUTH/3204/6/19.

Published evidence (Huisman et al, 2009; Barrière et al, 2019) show that medication errors are common and cause distress and clinical risk. Therefore, inclusion of pack shots and indications help patients distinguish between products and follow their prescribed regimen correctly.

Currently, pack shots are no longer visible on the landing page, instead, they are presented only after the patient has positively confirmed which IBSA medicine they have been prescribed. This adjustment further strengthens compliance, minimizes any residual risk of misunderstanding or misinterpretation, and is intended to reduce the risk of inadvertent promotion while maintaining a clear focus on reducing medication errors—a documented patient safety concern.

The patient section of the Fertility website is carefully designed to ensure that access is restricted to individuals already prescribed IBSA medicines, with content limited to practical and factual guidance supporting the correct use of treatment. The self-validation process and the display of pack shots are measures implemented to ensure robust compliance with all applicable PMCPA and ABPI Code requirements, in particular Clause 26.2. These controls reflect our proactive, ongoing commitment to meet the highest standards of regulatory practice. Accordingly, the website fully complied and continues to comply with the Code and relevant guidance and demonstrates IBSA's dedication to supporting patients responsibly and appropriately within the framework of the industry's best practices.

5. Summary and remedial actions

- We acknowledge and accept responsibility for the black triangle error, which constituted a breach of Clause 12.7 (misattributed as 12.10 in your original correspondence). This issue was promptly rectified, and a corrective and preventative action (CAPA) plan was implemented to ensure such errors do not recur.
- In all other respects, we respectfully submit that the websites comply fully with Clauses 5.1, 6.1, and 26.1 of the 2024 ABPI Code. All content has been certified, is factual, balanced, and provided solely for reference purposes in accordance with the requirements of Clause 26.2.

As part of our ongoing commitment to the highest standards of compliance and continuous improvement, we regularly review our corporate and therapy area websites. Following this complaint, we have undertaken an additional full review to further assure clear audience segmentation and further minimise any potential risk of misunderstanding or misperception.

IBSA UK remains committed to maintaining the highest standards of compliance and to upholding the Code in both letter and spirit."

PANEL RULING

This case was in relation to two websites from IBSA Pharma: the IBSA UK corporate website and the IBSA UK fertility website. The complainant alleged that the corporate website was not split between information for health professionals and that for the general public and patients on treatment. Citing specific webpages from the two websites, the complainant alleged that the availability of certain information to the general public constituted promotion of prescription only medicines to the public. The complainant further alleged that, on one of the webpages, the black triangles present were not the correct colour.

The Panel noted that Clause 6.1 had been raised by the case preparation manager but did not consider that an allegation had been made with respect to this clause. The Panel, therefore, ruled **no breach of Clause 6.1**.

Corporate website – Products page

Promotion to the public

The complainant alleged that the information on the Products page of the corporate website was available to all viewers, not just healthcare professionals. The complainant also stated that there was a link to the Silandyl summary of product characteristics (SPC) but no link to prescribing information and that they were unclear as to whether the SPC was being offered to the general public rather than the patient information leaflet. The Panel interpreted this to be an allegation that prescription only medicines were being promoted to the public, which was contrary to Clause 26.1 of the Code.

The Panel observed that the webpage was titled "Products" and appeared to be one of five tabs available on the main navigation bar of the website. Directly beneath the page header was the following text:

> *"This page contains information that is intended for residents of the United Kingdom only and is not meant to substitute for the advice provided by a medical professional. Always consult a healthcare professional if you have health concerns."*

An adverse event reporting statement, as per the wording specified in Clause 26.4, was present at the bottom of the page above the website footer.

The remainder of the webpage was split into four sections, each with a short list of products and accompanied by a graphic representing the therapeutic area: Reproductive medicine, Osteoarticular, Urogynaecology and Food Supplements.

The "Reproductive medicine" section listed five products by brand name and non-proprietary name. The last brand name also displayed an inverted triangle which was dark blue in colour. The meaning of the triangle was explained at the bottom of the section, with the wording specified in Clause 26.4. Underneath the list of products was the following: *"More information about these products can be found here: Members of the Public – IBSA Fertility*". The Panel understood this link to direct to the Public webpage of the IBSA fertility website which the complainant had also submitted allegations against.

The “Urogynaecology” section listed only one product, “Silandyl (Sildenafil)” with a link to the product’s SPC.

The “Osteoarticular” and “Food Supplements” sections each listed three products. The Panel understood that these were not prescription only medicines.

IBSA submitted that the webpage was fully aligned with Clause 26.2 of the Code which allowed companies to provide factual, balanced and non-promotional reference information about medicines for public access. IBSA further submitted that the content of the page was strictly limited to the names of the products, their pharmaceutical forms and links to the relevant SPCs – it contained no statements about efficacy, no comparative claims and no promotional statements or language.

Clause 26.1 of the Code stated that prescription only medicines must not be advertised to the public. Clause 26.2 allowed for the provision of non-promotional information about prescription only medicines to the public, including reference information made available by companies on their websites, provided such information was factual and presented in a balanced way. The supplementary information to Clause 26.2 stated that pharmaceutical companies are not obliged to provide reference information but it is considered good practice to provide as a minimum the regulatory information comprising the SPC, the patient information leaflet (PIL) and the public assessment report (PAR) (UK or European) where such a document exists.

The Panel noted the broad definition of promotion, and that the mention of a medicine and its indication together would most likely be considered promotional. Mention of a therapy area might also be considered promotional when used alongside the name of a medicine and each case would be decided on the facts of the case.

In the Panel’s view, the webpage contained a list of products attributed to very general therapeutic areas. The webpage did not contain any specific indications for the products, nor did it provide any further information or claims. A link to the SPC was provided for one product, however the Panel considered that this was permitted as reference information and noted that a reader would have to actively click to access the SPC and therefore any further information about the product.

On the evidence before it, the Panel did not consider that the ‘Products’ webpage constituted promotion of prescription only medicines to the public and, therefore, ruled **no breach of Clause 26.1**.

Black triangles
Clause 12.7 included the requirement that, when required by the licensing authority, all promotional material must clearly show an inverted black triangle to denote that additional monitoring is required in relation to adverse reactions.

The complainant alleged that the black triangles present on the Products webpage were not the correct colour – they were not black.

IBSA submitted that, due to a technical error by a third-party provider, a deep navy triangle had been used instead of a black one. IBSA submitted it was an isolated error which was rectified

immediately upon discovery, and a corrective and preventative action process was initiated to prevent recurrence. IBSA acknowledged a breach of Clause 12.7.

The Panel noted, however, that Clause 12.7 applied only to promotional material for health professionals and other relevant decision makers. Taking account of its ruling above, the Panel considered that the webpage had not been established to be promotional material. On this technical basis, the Panel therefore ruled **no breach of Clause 12.7**.

There was also a requirement (under Clause 26.4) for the black triangle symbol to be included on material which relates to a medicine and which is intended for patients taking that medicine. The Panel noted that, as the webpage was intended for members of the general public and not patients specifically, this clause was also not applicable and had not been raised by the case preparation manager.

However, in the Panel's view, the inverted black triangle was a well-known and established symbol. Its appropriate use was an important part of medicines regulation. Thus, in the Panel's view, failure to publish the triangle in the correct colour was, at the very least, inappropriate and might potentially cause confusion. The Panel considered high standards had not been maintained and ruled **a breach of Clause 5.1**.

Corporate website – Separation of information for different audiences

The complainant alleged that the corporate website did not appear to be split between information for healthcare professionals, information for the general public and information for patients on treatment. The complainant described the website as containing both information about the company and also the Products webpage described above.

The supplementary information to Clause 26.2 stated that a pharmaceutical company website providing information for the public as well as promotion to health professionals must have the sections for each target audience clearly separated and the intended audience identified. As Clause 26.2 had not been raised by the case preparation manager, the Panel considered the matter under the requirement for companies to maintain high standards (Clause 5.1).

IBSA submitted that reference information provided on the Products page was intended to inform and not promote, and so within this context, separate access restrictions or audience segregation were not mandated by the ABPI Code.

Taking account of its ruling above, the Panel considered that the Products webpage had not been established to be promotional for any prescription only medicines. The complainant had provided no further evidence to demonstrate that the IBSA UK corporate website contained promotional information. The Panel therefore ruled **no breach of Clause 5.1**.

Fertility website – Public page

The complainant stated the 'Public' webpage on the IBSA Fertility website mentioned products, included links to SPCs and had a safety statement for patients on treatment. The complainant alleged that by displaying information that should only be for patients on treatment, the webpage was promoting to the general public.

The Panel observed that the webpage was titled "Members of the Public" and appeared to be one of three tabs available on the main navigation bar of the website. The only content on the webpage was a section titled "Summary of product characteristics". Directly beneath the header was the following statement:

> *"This page contains information that is intended for residents of the United Kingdom only and is not meant to substitute for the advice provided by a medical professional. Always consult a healthcare professional if you have concerns."*

This was followed by a list of six medicines by brand name and non-proprietary name; next to each was a 'Download' link. The Panel understood that clicking on this link would download the relevant product's SPC. Underneath the list of products was a boxed warning detailing the black triangle statement as per the wording in Clause 26.4, and a separate boxed adverse event reporting statement also as per the wording in Clause 26.4.

IBSA submitted that the Fertility website was clearly segmented, with separate navigation for healthcare professionals, patients and members of the public. Within the public section, IBSA submitted that product names were listed and links to SPCs were provided as reference material, consistent with Clause 26.2. IBSA further submitted that the patient safety statement was included solely to highlight important safety considerations and encourage appropriate reporting of side effects, and that it did not constitute product promotion.

In the Panel's view, the webpage contained a list of fertility-related products. The webpage did not contain any specific indications for the products, nor did it provide any further information or claims. A link to the SPC was provided for each product, however the supplementary information to Clause 26.2 advised that whilst pharmaceutical companies are not obliged to provide reference information to the public, it is considered good practice to provide as a minimum the regulatory information, which includes the SPC. A reader would also have to actively click to access the SPC and therefore any further information about the product.

The Panel did not consider that the inclusion of a black triangle statement and an adverse event reporting statement, both requirements of material intended for patients taking a medicine, meant that the page was *only* suitable for patients or that it rendered the webpage promotional.

On the evidence before it, the Panel did not consider that the 'Public' webpage was only suitable for patients on treatment and therefore constituted promotion of prescription only medicines to the public. The Panel ruled **no breach of Clause 26.1**.

Fertility website – Patients page

The complainant stated the 'Patients' webpage on the IBSA Fertility website displayed not just the product a patient would have been prescribed, but others that they might not have been. The complainant alleged that this constituted promotion to the general public.

The Panel observed that the webpage was titled "Prescribed an IBSA medicine?" and appeared to be one of three tabs available on the main navigation bar of the website. Directly beneath the header was the following information:

> *"As a patient who has been prescribed an IBSA medicine, we understand that you may have some questions.*

In this section you will find all the information you need to support the use of your medication and your fertility journey going forward. Once you have selected the product that you have been prescribed, you will find a short video explaining how to prepare, inject and dispose of your treatment.

You will also find a patient pathway which identifies how each medication relates to the different stages of your fertility journey."

Beneath this text, four pack shot images of IBSA medicines were displayed (Fostimon, Lubion, Zivafert and Meriofert). Each pack shot was accompanied by the name of the product and a statement explaining the specific indication. For example:

[Pack shot image of Fostimon]
"Fostimon (Urofollitropin)

- *Fostimon is used to promote ovulation in women who are not ovulating and who have not responded to other treatment (clomifene citrate)*
- *It is used to bring about the development of several follicles (and therefore several eggs) in women receiving fertility treatment"*

The Panel noted IBSA's submission that the content of the webpage had been changed since receipt of the complaint and that pack shots were no longer visible when landing on the webpage and were only visible after a patient had confirmed which IBSA medicine they had been prescribed. The Panel made its ruling based on the appearance of the webpage at the time of the complaint, which included the pack shots.

IBSA submitted that before accessing the webpage, a reader would have to self-attest that they were a patient that had been prescribed an IBSA medicine. Once on the page, the information was tailored for those prescribed an IBSA medicine and was limited to a pack shot and a short overview made up of the licensed indication only. IBSA submitted this information was provided exclusively to enhance correct use and minimise medication errors in complex fertility regimens.

The supplementary information to Clause 26.1 stated, among other things, that information about medicines already prescribed for patients may be provided proactively, reactively or as reference information. Such material must be factual and non-promotional and clearly state the intended audience.

The Panel considered, however, that patients who were looking for information on one particular IBSA medicine would automatically be shown the pack shot, brand name, non-proprietary name and indication of other IBSA fertility medicines. The Panel noted the broad definition of promotion, and that the mention of a medicine and its indication together would most likely be considered promotional. In the Panel's view, the webpage in question therefore advertised prescription only medicines to the public and it ruled **a breach of Clause 26.1**.

The Panel considered that providing promotional information about other medicines might encourage patients to ask their health professional to prescribe these other medicines. The Panel took account of the therapeutic area of fertility and that patients might be particularly likely to seek medicines to help their situation. In the Panel's view, the wording at the top of the webpage also encouraged patients to consider the full list of medicines. In the Panel's view, the wording "*…you will find all the information you need to support the use of your medication and*

your fertility journey going forward" and *"…how each medication relates to the different stages of your fertility journey*" could give the impression to patients that they could or should be prescribed all these medicines at some point in their treatment, which might not be the case. Taking this into consideration, the Panel concluded that IBSA had failed to maintain high standards. The Panel ruled **a breach of Clause 5.1**.

Complaint received **5 September 2025**

Case completed **22 April 2026**