CASE/0600/05/25 ***NO BREACH OF THE CODE***

COMPLAINANT v GSK

Allegations about misleading information on GSK Pro website

CASE SUMMARY

This case was in relation to a Blenrep (belantamab mafodotin) webpage on a GSK promotional website. The complainant alleged that the webpage was misleading because although the webpage referred to two Blenrep treatment combinations, the progression-free survival and adverse reaction sections only provided data for the combination that had "better results". The complainant further queried whether the adverse reaction summary data truly represented a "summary" when data from only one combination was included.

The outcome under the 2024 Code was:

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
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 6.4	**Requirement that claims must reflect the available evidence regarding possible adverse reactions**

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 was received about GSK from an anonymous, non-contactable complainant who described themselves as a health professional.

COMPLAINT

The complaint wording is reproduced below, with some typographical errors corrected:

> "To whom it may concern. Following attendance at BSH and hearing about Blenrep, I searched for information through the GSK website and I would like to issue a complaint. I was searching to find data by clicking on the discover button which led me to this next link: [URL provided]. But I feel like I am being tricked. GSK are selling on their website by using the idea that the Blenrep has two combination options but they are only showing data from the combination that has better results (Vd not Pd) - this is the case

> for the PFS [progression-free survival] box and the adverse reaction box. It is very misleading. To make it worse, the adverse reaction box title is that it is a summary. I question if this truly represents a 'summary' if only one combination data is included and the website is clearly about both. I request you assess if they are breaking 2, 5.1, 6.1, 6.4."

When writing to GSK, the PMCPA asked it to consider the requirements of Clauses 2, 5.1, 6.1 and 6.4 of the 2024 Code.

GSK'S RESPONSE

The response from GSK is reproduced below, with some typographical errors corrected:

> "GSK was extremely disappointed to have received a letter dated 6th June 2025 from the PMCPA informing us of a complaint from an individual describing themselves as a healthcare professional regarding the above. The PMCPA has asked us to consider clauses 6.1, 6.4, 5.1 and 2 of the 2024 ABPI Code of Practice (the code).
>
> The complaint concerns the presentation of information on the GSK promotional BLENREP webpage (Internal job code PM-GB-BLM-WCNT-250001); specifically, the data shown under the Progression-Free Survival (PFS) and the summary of safety profile sections. The complainant alleges that the website is misleading by presenting results from only one of the licensed combinations for Blenrep (*Belantamab mafodotin with bortezomib and dexamethasone* - BVd) while excluding data from the other (*Belantamab mafodotin with pomalidomide and dexamethasone* - BPd), despite the page appearing, in their view, to introduce both combinations. They have alleged a breach of clauses 2, 5.1, 6.1, and 6.4.
>
> GSK takes its responsibility in abiding by the letter and the spirit of the Code and all other relevant UK rules and regulations very seriously. Following the complaint, we have completed a thorough review of the relevant webpages in question, as well as whether our internal ways of working were followed correctly. Following the review, GSK is confident that our processes were followed correctly and the materials in question are of suitable quality and of a high standard and comply with the Code. Consequently, we refute breaches of clauses 6.1, 6.4, 5.1 and 2 of the Code.
>
> GSK has laid out specific responses to the individual clauses the PMCPA has asked us to consider in detail below.
>
> **Website background**
> The Blenrep▼ (belantamab mafodotin) webpages referred to in the complaint are part of a more extensive promotional website called GSKPro, for UK Healthcare Professionals (HCPs) only. Users are required to declare themselves as healthcare professionals before being granted access to the site. The website contains promotional information about GSK medicinal products currently promoted in the UK. Within the website there is a section dedicated to the product Blenrep.
>
> Blenrep was granted marketing authorisation (MA) by the MHRA on 17/04/2025 (full license wording outlined below). Additional data generation and publication are still ongoing. At the time of the complaint, Blenrep was still in the launch phase of this new

license, with MA granted but reimbursement negotiations still on-going with NICE, and therefore the webpages provide a summary of the most relevant safety and efficacy data to a UK audience at that time. GSK is in the process of updating the webpages to include much more detailed data as they emerge, including those published since the date of the complaint. This is part of GSK's efforts to continually improve and update materials (including webpage content) in line with available evidence.

GSK processes and structure

GSK has robust processes and structures in place for material approval to ensure compliance with the Code, GSK's own code, and UK regulations. All employees involved in copy approval must complete mandatory GSK copy approval SOP training. Each brand team holds a regular Forum for Discussion and Approval (FDA), including the medical and commercial teams, to discuss materials requiring copy approval, to align fully between functions and ensure that content is code compliant. Where views differ, such as those over specific claims, there is a clear and well-established route of escalation for resolution.

To maintain high standards of ongoing Code knowledge, GSK conducts a monthly Code and Governance Forum meeting in which Code cases are presented and discussed as well as any other compliance/governance issues. This meeting is for all staff involved in activities and the development of materials within scope of the ABPI Code. It is mandatory for all medical signatories and AQPs to attend a minimum of 8 sessions per year for their on-going development. All materials discussed are stored on GSK's internal governance platform, and accessible to all UK staff.

Additionally, GSK holds a signatory and medical project forum once a month for all medical signatories and medical reviewers. The meeting is a platform for attendees to raise Code- and other governance/compliance-related agenda items for discussion.

Furthermore, GSK has a fair and objective process for assessing and validating not only medical signatories and AQPs, but also commercial reviewers. The role of the commercial reviewer is to provide commercial overview of all promotional and relevant non-promotional materials for appropriateness, including fundamental aspects and principles of the Code, content suitability and strategic alignment. The validation assessments involve one or two experienced assessors, objectively testing candidates' code knowledge centred on scenario examples most of which are based on real code cases. The scenarios/examples, cover a wide breadth of the Code. In addition, the appraisee must have completed a set of mandatory training requirements. In the case of medical signatories, the appraisee must have been mentored for a suitable period of time by another experienced medical signatory, until deemed ready to take the assessment to become a final medical signatory by their mentor and their line manager.

Blenrep and disease background

Blenrep, is a first-in-class, B-cell maturation antigen (BCMA)-binding antibody-drug conjugate (ADC) containing monomethyl auristatin F (MMAF)7 which eliminates myeloma cells by a multimodal mechanism involving direct cell killing and activation of

anti-myeloma immune responses. On 17/04/2025, the MHRA granted the following licenses for Blenrep in the UK:

In the UK, Blenrep is indicated in adults for the treatment of multiple myeloma:

- *in combination with bortezomib and dexamethasone (BVd) in patients who have received at least one prior therapy; and*
- *in combination with pomalidomide and dexamethasone (BPd) in patients who have received at least one prior therapy including lenalidomide.*

The marketing authorisation for Blenrep is based on the primary analysis of two different registrational phase 3 studies (DREAMM-7 and DREAMM-8) and therefore covers two distinctly different populations of patients with multiple myeloma.

DREAMM-7 is a multicentre, open-label, randomised phase III clinical trial evaluating the efficacy and safety of belantamab mafodotin combined with bortezomib plus dexamethasone (BVd) compared to daratumumab combined with bortezomib plus dexamethasone (DVd) in patients with relapsed/refractory multiple myeloma who previously were treated with at least one prior line of multiple myeloma therapy.

DREAMM-8 is a multicentre, open-label, randomised phase III clinical trial evaluating the efficacy and safety of belantamab mafodotin in combination with pomalidomide plus dexamethasone (BPd) compared to bortezomib and pomalidomide plus dexamethasone (PVd) in patients with relapsed/refractory multiple myeloma previously treated with at least one prior line of multiple myeloma therapy, including a lenalidomide-containing regimen.

Table 1 Summary of DREAMM-7 and DREAMM-8 Phase III Clinical Trials
(Both trials are multicentre, open-label, randomised studies evaluating efficacy and safety in patients with relapsed/refractory multiple myeloma who received ≥ 1 prior line of therapy)

Trial Name	Treatment Arms	Patient Population	Reimbursement Status
DREAMM-7	- **BVd**: Belantamab mafodotin + bortezomib + dexamethasone [UK's standard of care for 2L RRMM] - **DVd**: Daratumumab + bortezomib + dexamethasone	Relapsed/refractory multiple myeloma patients who received ≥ 1 prior line of therapy	Draft Guidance [ID6212] published 12 June 2025

DREAMM-8	- **BPd**: Belantamab mafodotin + pomalidomide + dexamethasone - **PVd**: Pomalidomide + bortezomib + dexamethasone	Relapsed/refractory multiple myeloma patients who received ≥ 1 prior line of therapy, **including lenalidomide**	Negotiations on- going **[ID6211]** Initial draft guidance does not recommend use

Prior to these newly licensed combinations, the main standard-of-care (SoC) option for adult patients in the UK with multiple myeloma at first relapse was DVd. This is also the case globally, hence why it was used as the comparator arm in DREAMM-7.

It is important to note that the PVd triplet combination used as a comparator in DREAMM-8, is not currently reimbursed by NICE for use in second line myeloma in England and Wales. For this reason, UK HCPs have little to no experience with this combination and have previously questioned its relevance to the UK market during interactions with GSK staff, given the lack of clinical context in which to interpret the results of the trial. This is reflected in the fact that, whilst the data was conclusive enough for Blenrep to be issued marketing authorisation by the regulators, NICE has recently (27/06/25) published initial negative guidance on the use of the BPd combination (subject to further negotiations).

As already mentioned, the two trials recruited from two clinically distinct patient populations, with DREAMM-8 recruiting only lenalidomide exposed patients (this was not an inclusion criterion in DREAMM-7).

GSK would like to highlight this point, as it is well-reported in the medical literature that patients previously exposed to lenalidomide experience worse outcomes in later lines of treatment. This is therefore a well-known fact to UK HCPs who are familiar with treating patients with relapsed/refractory multiple myeloma.

GSK also believes that it is relevant to explain that the DREAMM-7 trial recruitment period was between May 2020 and June 2021, whilst the DREAMM-8 trial recruitment period didn't start until 5 months later occurring between Oct 2020 and Dec 2022. The available published data for DREAMM-7 is therefore more mature with a much longer follow-up than the data for DREAMM-8. This is demonstrated by the fact that, at the time of the complaint the median progression free survival (mPFS) had not been reached in DREAMM-8, whereas it had in DREAMM-7. Median PFS is widely accepted to be a robust clinical endpoint amongst specialist UK HCPs. Despite this, the less mature data available from DREAMM-8 was still relevant and conclusive enough for the regulators to issue a marketing authorisation for both combinations. Please see table (Table 1) for a summary of the data alongside the reimbursement status for each combination.

The final difference between the trials, that GSK would like to bring to the panel's attention, is that the two studies were designed with significant differences in dosing regimens. DREAMM-7 moved to belantamab monotherapy after 8 cycles, whereas

DREAMM-8 maintained triplet therapy throughout the course of the trial and allowed for dose-reductions to a much lower dose intensity than DREAMM-7.

Based on the context provided above and in summary:

- The DREAMM-7 trial data is more relevant to UK HCPs due to its mature data and the comparator arm reflecting the UK standard of care. Whilst both combinations are licensed for use in the UK; at the time of complaint BVd was expected to be accessible in the UK much earlier than BPd, owing to the status of NICE negotiations (At the time of writing this defence, draft NICE guidance for BVd has been published ID 6212). Negotiations are on-going with NICE regarding reimbursement for BPd.
- GSK asserts that promoting one licensed Blenrep combination over another is permissible under the code. Furthermore, omitting information about the availability of two licensed combinations before highlighting the more relevant data would risk creating a false impression of limited options, leaving UK HCPs less informed.
- As defined in clause 14.1 of the code, GSK contends that it is not good clinical practice to compare data across clinical trials which differ significantly on several aspects. GSK therefore strongly contends that the accusation of selecting a "better data set'' which implies one dataset is superior to the other, is neither scientifically accurate nor of relevance in this case.

Having provided the context, GSK would now like to address the complaint specifically and address each of the relevant clauses that we have been asked to consider by the PMCPA:

Clause 6.1

Clause 6.1 states that information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence clearly. They must not mislead either directly or by implication, by distortion, exaggeration, or undue emphasis. Material must be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine.

The complainant has alleged that they feel 'tricked' because GSK are claiming to have two combinations but are only showing data from 'the combination with better results – this is the case with the PFS box and the adverse events box.', therefore suggesting the page is misleading and lacks substantiation. GSK has limited its response to the sections highlighted by the complainant only.

GSK will address the claims in the order in which they are presented on the webpage.

The complainant has referred to the claim on the GSK webpage that reads 'BLENREP offers two different treatment combinations to meet your patients' needs: BVd and BPd'. This claim is a statement of fact that stands alone as described above and can be fully substantiated by our licensed indications stated verbatim from the SmPC below the claim in question.

As already described above, Blenrep has two distinct marketing authorisations based on separate clinical trials with different comparator arms, study designs, and patient

populations, resulting in two licensed indications for adult multiple myeloma patients. Neither of these two licensed indications conflict with or contradict each other but rather allow for the use of Blenrep in a wider number of patients. GSK asserts it is not obligated to promote both indications and has chosen to focus on one to better support UK HCPs, despite potential disadvantages to GSK. GSK would like to state that the intention of promotion is to encourage the rationale use of medicines within their respective licensed indications. The webpage in question presents data from the licensed combination that is most clinically relevant and widely available to prescribe in the NHS but that this does not detract from the ability of clinicians to choose to prescribe the alternative combination after reviewing the SmPC (available via single click link on the page), with the proviso that access to the BPd combination would involve channels normally available in the absence of reimbursement.

Regarding the complainant's allegation that GSK have used 'better data' or been guilty of cherry picking, GSK reaffirms that it is poor clinical practice to compare data across two different trials with different populations and trial designs, in line with the guidance provided in clause 14.1 of the Code. GSK notes that the complainant has failed to provide any evidence to support their accusation.

Even if it were appropriate to compare trials, GSK would like to highlight some fundamental points to illustrate reasons why we believe the complainant's argument is based on incorrect assumptions. The data presented in the efficacy box on the webpage, is for median PFS for the BVd combination, as already mentioned earlier. Similar published median PFS data was not available for the BPd combination until after the complaint was received by GSK. The PFS data that was available for BPd/DREAMM-8 at the time of the complaint was the 12 month PFS rates. Whilst the 12 month PFS data was still a valid endpoint for the regulators to issue a marketing authorisation for the indication, median PFS is widely acknowledged as the optimal surrogate endpoint for overall survival, the gold standard efficacy endpoint in myeloma treatment. The median PFS data for BPd was presented for the first time at a later date, at the [named congress] on the 13/06/25 i.e. after the complaint was received by GSK. The delay in availability of this data reflects the differences in timeline between the two the clinical study programmes for the two combinations as already referred to above.

The table below (Table 2) provides a summary of the data available for the two treatment combinations at the time of the complaint.

Table 2 Summary of data available at the point GSKPro went live (30/04/25):

		Efficacy			**Safety overview**	
Trial name	**Arms**	**mPFS (Months, 95% CI)**	**HR, (95% CI)**	**p-value**	**DC rate**	**Fatal AEs**
	BVd (n=243)	36.6 (28.4, NR)	0.41	<0.000	31%	10%

DREAMM-7	**DVd** (n=251)	13.4 (11.1, 17.5)	(0.31,0.53)	01	19%	8%
DREAMM-8	**BPd** (n=155)	**NR** (20.6, NR)	0.52 (0.37, 0.73)	<0.001	15%	11%
	PVd (n=147)	12.7 (9.1, 18.5)			12%	11%

AE – adverse events; BVd – belantamab mafodotin plus bortezomib and dexamethasone; DVD – daratumumab plus bortezomib and dexamethasone; BPd - bortezomib plus pomalidomide and dexamethasone; NR – not reached, PVd – pomalidomide plus bortezomib and dexamethasone DC – discontinuation; HR – hazard ratios; mPFS – median Progression free survival

To emphasize the importance of comparing like-for-like outcome data with similar maturity levels, as outlined above, the median PFS data from DREAMM-8 was immature at the time of the complaint, as shown in Table 2. However, recent mature median PFS data from DREAMM-8 presented at EHA in June 2025 aligns closely with BVd/DREAMM-7 (mPFS: BVd vs DVd = 36.6 vs 13.4 months, HR 0.41 [0.31,0.53]; BPd vs PVd = 32.6 vs 12.5 months HR 0.49 [0.35,0.68]). While trial design and patient population differences limit direct comparisons, the data further refutes the complainant's claim that GSK selectively presented data.

The complainant has questioned whether the box entitled “Summary of safety profile” truly represents a “summary”. GSK contends that it is a well-established principle of the code that appropriate safety information must be presented to balance any efficacy claims made in promotional materials. To this end, the safety information presented adjacent to the BVd efficacy data also relates to BVd. GSK submits that this is the correct approach and meets the requirements of the code in terms of providing safety information as a balance to efficacy claims. Furthermore, GSK contends that it is transparent and explicit that the safety information provided relates to BVd, a fact also acknowledged by the complainant in their complaint, and that UK HCPs will not therefore be left with any confusion for this reason.

GSK would like to highlight that in DREAMM-7, BVd demonstrated a higher incidence rate of adverse events, a higher rate of dose delays due to adverse events, a higher rate of dose reductions due to adverse events and a higher rate of discontinuations due to adverse events, BPd did show a higher rate of fatal events but only by a margin of 1% (11% vs 10% - refer to Table 2). The most commonly observed adverse events are very similar between the two combinations, with the exception of three AEs which are as a result of the combination drugs in the BPd triplet (neutropenia, fatigue and pneumonia) rather than Blenrep (Please see very common adverse events in Pomalidomide SmPC).

To summarise, GSK strongly feels that the efficacy and safety information provided on the webpage is accurate, balanced, fair, objective and unambiguous and is based on an up-to- date evaluation of all the relevant evidence. GSK holds two clinically distinct licenses and has chosen to promote the combination that best serves its HCPs. Importantly the data from the DREAMM 8 trial, not shown on the webpage, does not

influence in any way the prescribing for patients of Blenrep in combination with bortezomib and dexamethasone (BVd); the combination currently available for prescription on the NHS. The data presented on the page is very clear and unambiguous as the text makes it explicitly clear which combination of treatment with Blenrep is being referred to, along with all other relevant pre-requisite information necessary to support the claim appropriately. Indeed, the complainant themselves was clearly able to identify that the data was for the BVd combination as referred to in their complaint. Finally, the complainant has not substantiated claims of cherry-picking data by providing any data to corroborate their assertion and appears to be suggesting unfounded cross-trial comparisons.

GSK therefore maintains that, in the spirit of Clause 6.1, we have presented a balance of efficacy and safety data to ensure a busy HCP reading our page can form their own opinion on the therapeutic value of the relevant combination (BVd) GSK also contends that we have not misled the relevant audience either directly or by implication, by distortion, exaggeration, or undue emphasis. GSK submits that the webpage is sufficiently complete to enable UK HCPs to form their own opinion of the therapeutic value of the medicine. GSK therefore strongly denies a breach of clause 6.1.

Clause 6.4

Clause 6.4 states that: “Information and claims about adverse reactions must reflect available evidence or be capable of substantiation by clinical experience. It must not be stated that a product has no adverse reactions, toxic hazards or risks of addiction or dependency. The word ‘safe’ must not be used without qualification.”

As already described above, GSK has presented the available safety evidence for the most clinically relevant combination available for access of Blenrep for multiple myeloma by UK HCPs in the NHS. This information can be fully substantiated by the Summary of Product Characteristics (SmPC) for the product, which GSK contends is the most complete and robust source of information, having been reviewed and approved by the regulators.

Furthermore, the safety information provided does not state that BVd has no adverse reactions, toxic hazards or risk of addiction or dependency, and neither has the word “safe” been used. On the contrary, GSK has been very transparent about the incidence of adverse events and encourages the reader to access further information via the prescribing information (PI). In the case of Blenrep this consists of the entire SmPC along with the legal classification and cost list price included to ensure that all the details are available in full. The webpage has a very clear reference to where the link to the prescribing information (PI) can be found at the very top of the webpage irrespective of whether the reader scrolls up or down the webpage so that the information is easy to access at all times.

For these reasons, GSK strongly denies a breach of clause 6.4.

Clause 5.1

As described in detail above, GSK has robust processes, training, compliance, governance and management monitoring in place to ensure high standards and compliance with the code, and relevant UK regulations. GSK contends that the materials in question are of an adequately high standard as detailed above. The page was

certified by a qualified ABPI Final Medical signatory who is a pharmacist by background and with over 18 months experience of being a signatory.

GSK therefore contends that high standards have been maintained and therefore strongly deny a breach of clause 5.1

Clause 2

The PMCPA also asked GSK to consider Clause 2 of the Code. As stated in the code, GSK notes that a ruling of a breach of Clause 2 is a sign of particular censure and is reserved for such circumstances, including prejudicing patient safety and/or public health etc. It is ruled when significant failings have been identified, that include inter alia a risk to patient safety.

As set out in detail above, GSK has robust processes and ways of working in place to ensure high standards for materials review, which were followed in this case. Also, as established above, the efficacy and safety information provided clearly and very transparently on the webpage applies to the most appropriate and relevant combination that UK HCPs are likely to be able to prescribe in their clinical practice. Furthermore, GSK strongly contends that the amount of safety information provided is adequate to counterbalance the amount of efficacy data presented, GSK therefore also contends that UK HCPs making prescription decisions based on the totality of the information provided on the webpage would not be left with any confusion about it. Patient safety would not therefore be compromised. For these reasons, and all others detailed above, GSK contends that the activities and materials do not risk bringing discredit upon or reducing confidence in the pharmaceutical industry. Consequently, GSK refutes that there has been a breach of Clause 2."

PANEL RULING

This case was in relation to a Blenrep (belantamab mafodotin) webpage on a GSK promotional website. The complainant alleged that the webpage was misleading because although the webpage referred to two Blenrep treatment combinations, the progression-free survival (PFS) and adverse reaction sections only provided data for the combination that had "better results". The complainant further queried whether the adverse reaction summary data truly represented a "summary" when data from only one combination was included.

At the time of complaint, in accordance with its Summary of Product Characteristics (SPC) dated 17 April 2025, Blenrep was indicated for the treatment of adult patients with multiple myeloma:

- in combination with bortezomib and dexamethasone (BVd) in patients who have received at least one prior therapy
- in combination with pomalidomide and dexamethasone (BPd) in patients who have received at least one prior therapy including lenalidomide.

The Panel observed that the version of the webpage submitted by GSK (date of preparation: June 2025) differed slightly to the screenshot taken by the case preparation manager at the time of complaint in May 2025 (date of preparation: April 2025), which the Panel based its ruling on.

The complaint concerned the 'About Blenrep' webpage within the Blenrep section of the GSKPro website. The webpage began with a banner which stated, "BLENREP▼ (belantamab

mafodotin) combinations are now licensed in the UK for adult patients with multiple myeloma who have failed at least one prior line of therapy". This was followed by a banner which included the text "Discover BLENREP▼ (belantamab mafodotin) at first relapse in multiple myeloma. Offer a change in mechanism of action to your patients at first relapse with BLENREP, the first approved BCMA [B-cell maturation antigen] ADC [antibody drug conjugate] treatment for use in multiple myeloma".

The allegations related to the bottom section of the webpage which appeared beneath a mechanism of action video for Blenrep. This section was headed "BLENREP offers two different treatment combinations to meet your patients' needs: BVd and BPd". Directly underneath the heading was a short description of the two key clinical trials for Blenrep: DREAMM-7 and DREAMM-8. Beneath the trial description were four tiles, each containing a heading followed by a further explanatory statement underneath.

1. The first tile consisted of the headline claim "59% reduction in risk of progression or death with BLENREP + Vd vs DVd" and stated "BLENREP + Vd demonstrates superiority vs DVd with a median PFS of 36.6 months vs 13.4 months, offering patients the chance for a longer life." In much smaller font, read "Median progression-free survival was 36.6 months (95% CI: 28.4-not reached [NR]) in the BVd group and 13.4 months (95% CI: 11.1-17.5) in the DVd group. HR for disease progression or death, 0.41; 95% CI: 0.3-0.53; p<0.00001)".
2. The second tile, headed "Summary of safety profile", stated "The **most frequent*** adverse reactions in BVd included reduced visual acuity, thrombocytopenia, corneal examination findings, blurred vision, dry eye, photophobia, foreign body sensation in eyes, eye irritation, eye pain, diarrhoea, and upper respiratory tract infection". The cited footnote, in small font, read "*'Most frequent' is defined as occurring in ≥20% of patients in DREAMM-7".
3. The third tile, headed "Short infusion time and no mandated pre-medication", stated "BLENREP offers your patients a 30-minute infusion time, with no mandated hospitalisation, pre-medication or post-infusion monitoring mandated as per SmPC".
4. The fourth and final tile, headed "Patients maintain quality of life with BLENREP + Vd or + Pd", stated "Patients report comparable quality of life with BLENREP + Vd (vs DVd) or + Pd (vs PVd) as measured by EORTC CLQ-C30".

The indication, as outlined above, and link to prescribing information for Blenrep appeared beneath the tiles.

Clause 6.1

The Panel interpreted the complainant's allegation to be that the webpage was misleading because it referred to two treatment combinations for Blenrep, BVd and BPd, but presented progression free survival and adverse reaction data from BVd only which was the combination that had "better results".

The Panel considered there were two aspects to the allegation for it to consider: firstly, whether the presentation of the section misleadingly implied that the efficacy and safety information applied to both Blenrep treatment combinations; and secondly, whether the data had been selectively presented data from the combination with "better results".

The section at issue was headed with the claim “BLENREP offers two different treatment combinations to meet your patients’ needs: BVd and BPd” beneath which was brief details of the DREAMM-7 and DREAMM-8 clinical trials conducted for each combination. In the Panel’s view, this, together with the references to both licensed combinations elsewhere on the webpage, such as within the preview of the mechanism of action video and directly beneath the tiles, could reasonably give the impression that the information presented in the section related to both treatment combinations. The Panel considered this impression was further compounded by the content of two of the tiles: “Short infusion time and no mandated pre-medication”, which referred generally to Blenrep treatment, and “Patients maintain quality of life with BLENREP + Vd or + Pd”, which expressly referred to both combinations.

However, despite the impression, the Panel noted that the efficacy and safety information made no reference to BPd. In this regard, the first two tiles referred specifically to the BVd combination, citing efficacy PFS data and the most frequent adverse reactions in BVd from the DREAMM-7 trial. No reference was made to DREAMM-8.

GSK submitted that the marketing authorisation for Blenrep covered two distinct populations of patients with multiple myeloma as it was based on two different phase III clinical trials, DREAMM-7 and DREAMM-8.

GSK refuted that data had been selected because it represented better results, submitting that it was poor clinical practice to compare across trials with different designs and patient populations and that the complainant had not provided evidence to support their allegation of cherry picking.

In relation to the first tile that presented efficacy data, GSK submitted that it did not have mature, median PFS data available for BPd, as included for BVd at the time of the complaint. GSK stated that the data available at the time was 12-month PFS rates, which was sufficient for regulators to issue a marketing authorisation but not considered the gold standard efficacy endpoint in myeloma treatment.

In relation to the safety tile that presented the most frequent adverse reactions for BVd from the DREAMM-7 trial, the Panel noted GSK’s submission that these were very similar between the two trials, with exception to neutropenia, fatigue and pneumonia which were attributable to the combination drugs in the BPd triplet rather than Blenrep.

GSK stated that promoting one licensed Blenrep combination over another was permissible under the Code and that the webpage focussed on the licensed combination, BVd, that it considered most clinically relevant. In this regard, GSK submitted the DREAMM-7 trial data was more relevant due to its mature data and the comparator arm reflecting the UK standard of care. GSK further submitted that, at the time of the complaint, the BVd combination was expected to be accessible earlier in the UK due to the status of NICE negotiations being in draft, while negotiations were ongoing with NICE for BPd.

The Panel noted GSK’s submission that it was not obligated to promote both indications and that it had chosen to focus on BVd, in light of the contents of the section at issue. Noting GSK’s implication that it only promoted BVd, the Panel queried why information relating to BPd extended beyond the licensed indication section. In this regard, the Panel considered the section heading referred to both treatment combinations to meet “patients’ needs”, along with an outline of each clinical trial, and BPd was explicitly referenced to support claims regarding quality of life in the fourth tile (“Patients maintain quality of life with Blenrep + Vd or + Pd”).

Nonetheless, whilst the Panel considered that it might have been helpful and more complete for GSK to have included data on the BPd combination, particularly given the overall impression created by the header of the section, the Panel considered, on balance, that the wording of the tiles made clear which treatment combination the information related to. The Panel further considered that the complainant had not established that the data presented had been selectively chosen as a result of favourable results for BVd over BPd. It was not for the Panel to infer reasons to support a complaint.

On the narrow allegation and evidence before it, the Panel ruled **no breach of Clause 6.1** of the Code.

Clause 6.4

The complainant further queried whether the second tile, titled "Summary of safety profile", truly represented a summary when it included data from only one combination.

The Panel observed, as outlined above, that this tile listed the most frequent adverse reactions observed in patients receiving BVd, which was explicitly stated within the tile. The accompanying footnote further cited the DREAMM-7 trial, albeit in smaller font.

Clause 6.4 included, among other things, that information and claims about adverse reactions must reflect available evidence or be capable of substantiation by clinical experience. It must not be stated that a product has no adverse reactions, toxic hazards or risks of addiction or dependency.

Whilst the Panel considered that it would have been more complete for GSK to have included safety information for the BPd combination, given the overall impression created by the header of the section, it was clear, on balance, that the adverse reaction information related to the BVd combination. Based on the narrow allegation before it, the Panel considered the complainant had not established that the information about the adverse reactions did not reflect available evidence or was not capable of substantiation by clinical experience. The Panel therefore ruled **no breach of Clause 6.4** of the Code.

High standards and discredit

The complainant cited breaches of Clauses 5.1 and 2. The Panel noted its rulings of no breaches of the Code, and in the absence of any other allegations, evidence or factors, the Panel concluded it had not been established that GSK had failed to maintain high standards nor that discredit had been brought upon the industry in this regard. The Panel ruled **no breaches of Clause 5.1 and 2**.

Complaint received **29 May 2025**

Case completed **9 February 2026**