**CASE AUTH/3720/12/22** ***NO BREACH OF THE CODE***

# COMPLAINANT v GLAXOSMITHKLINE

## Allegations about a promotional email

### CASE SUMMARY

**This case was in relation to a promotional Blenrep (belantamab mafodotin) email sent on behalf of GlaxoSmithKline which was allegedly unsolicited and imbalanced.**

**The Panel ruled no breach of the following Clauses of the 2021 Code as it appeared the complainant had provided prior permission to receive promotional emails and their interest in multiple myeloma could be reasonably assumed, noting the specialty under which they had registered**:

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| **No Breach of Clause 5.1** | **Requirement to maintain high standards** |
| **No Breach of Clause 5.6** | **Requirement that material should only be provided or made available to those groups of people whose need for or interest in it can reasonably be assumed** |
| **No Breach of Clause 15.5** | **Requirement to obtain the prior permission of recipients for promotional emails** |

**The Panel ruled no breach of the following Clauses of the 2021 Code with regard to the balance of content within the promotional email as it did not consider that the omission of results that were not in line with the licensed indication at the time of the complaint rendered the email misleading:**

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|---|---|
| **No Breach of Clause 6.1** | **Requirement that information, claims and comparisons are balanced, sufficiently complete and not misleading** |
| **No Breach of Clause 15.5** | **Requirement to obtain the prior permission of recipients for promotional emails** |

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

### FULL CASE REPORT

A health professional complained about an unsolicited promotional email for BLENREP (belantamab mafodotin) sent on behalf of GlaxoSmithKline. Blenrep (belantamab mafodotin) was indicated for the treatment of multiple myeloma.

### COMPLAINT

The complainant submitted that they had received an unsolicited promotional email which promoted a GlaxoSmithKline product and provided a copy of the email at issue.

They stated that they had never given consent to receive promotional material to the email address nor did they treat patients with multiple myeloma.

The complainant further submitted that the material was imbalanced as it did not make mention of the recent failure of this product in a Phase III confirmatory trial which led to its withdrawal from several international markets.

When writing to GlaxoSmithKline, the Authority asked it to consider the requirements of Clauses 5.1, 5.6, 6.1 and 15.5 of the 2021 Code.

**GLAXOSMITHKLINE'S RESPONSE**

GlaxoSmithKline stated the complaint from a consultant/interim working in the oncology therapeutic area in the United Kingdom and European Union had made allegations regarding a Blenrep (belantamab mafodotin) promotional email (PM-GB-BLM-EML-220011; date of preparation December 2022, copy provided) sent via a publisher of an online platform for health professionals. GlaxoSmithKline took the complaint very seriously and was committed to following both the letter and the spirit of the ABPI Code of Practice and all other relevant regulations. Upon receipt of the complaint, GlaxoSmithKline instructed the third-party media agency and the publisher to pause all third party email activity for Blenrep with immediate effect, whilst the complaint was being investigated.

GlaxoSmithKline stated that the Authority had asked them to respond with regards to Clauses 5.1, 5.6, 6.1 and 15.5 of the 2021 Code.

GlaxoSmithKline's position was that it had complied with the requirements of the Code and denied breaches of these clauses, with the reasoning as detailed below.

**Targeted email promotion to relevant and consenting healthcare professionals**

GlaxoSmithKline stated the promotional email in question was used as part of a third party email program, run through the publisher of an online platform for health professionals.

The platform was an online global platform for physicians and health professionals, offering medical news, expert perspectives, disease information, reference materials and continuing medical education (CME). Membership was free and users must register for an account in order to access the full range of online resources. During the registration, the user must provide their email address, indicate their country of practice, select their profession from a drop-down menu, indicate their primary area of practice/primary specialty and enter their work postal code. Registering users must agree to the platform's terms of use and privacy policy and there was an optional tick box to indicate consent to receive relevant information from industry.

IIn the third party email program that was used, a triggered email was sent to a platform member within 24-48 hours of the member clicking on and opening a link to an article on the platform where the lead condition was identified by the platform's editorial group as multiple myeloma, or an article with a substantial amount of multiple myeloma content, as determined by its editorial group.

GlaxoSmithKline stated the triggered email in question was developed by GlaxoSmithKline and was approved by GlaxoSmithKline's medical review team. The email was reviewed and

certified, and the final form was inspected and approved on 1 December 2022 by a registered pharmacist, a copy of the certificate was provided.

In order for a health professional to receive the triggered email, the following criteria were required to be met:

- The health professional must have provided an email address and consent to receive promotional information from pharmaceutical companies via the platform's publisher, by proactively opting in to 'receive relevant information from industry' during the platform's registration process.
- The health professional must be logged into the platform's website.
- The health professional must have clicked on and opened at least one page on the platform's website tagged with multiple myeloma as the lead condition or with a substantial amount of multiple myeloma content within the previous 24 to 48 hours.

GlaxoSmithKline stated that upon receipt of the complaint, the publisher checked the internal set up for this campaign and confirmed that no errors had been made in the set up and delivery of this campaign, in line with the above criteria (copy provided).

**Ensuring recipients of the promotional email had provided the required permissions**

GlaxoSmithKline purchased the promotional email program via a third-party media agency. As part of GlaxoSmithKline's agreement with the agency, the agency conducted a vendor screening process to ensure appropriate consent management monitoring. Through this process, the platform's publisher had certified that they obtain the necessary and specific consent from individuals to receive promotional emails from pharmaceutical companies, and direct marketing via email only occurs with opt-in consent, (copy provided).

As stated above, the platform's publisher confirmed that there were no errors in the set-up and delivery of this campaign, and email recipients, at the time of send, had consented to receive promotional emails from pharmaceutical companies (copy provided).

In order to ensure compliance with data privacy regulations, GlaxoSmithKline had not sought to confirm the consent status of the individual complainant with the platform's publisher, and instead had sought assurance that all recipients of the email in question had consented to received promotional emails from sponsors (copy provided).

GlaxoSmithKline stated they had no input into the mailing list. Individuals who received the triggered email had consented to receive promotional emails from pharmaceutical companies via the platform's publisher, as opposed to consenting to receive promotional emails directly from GlaxoSmithKline. The wording of the opt-in consent, explicitly stating that health professionals who opt-in may receive promotional emails from pharmaceutical companies (copy of the wording was provided).

All members included in promotional campaigns have given explicit consent to receive promotional emails from pharmaceutical companies. During the registration process, the optional tick box where users can actively confirm consent to the statement *'I would like to receive relevant Information from Industry*' directs the user to the following asterisked footnote: *Information from Industry emails from [the platform's publisher] (which operates [the platform]) contain product and/or promotional information from our business partners, including*

*pharmaceutical and medical device companies. Your email address will not be shared with these partners and you can unsubscribe at any time.*

If a member had not actively consented to receive promotional emails, they would be excluded from all promotional email campaigns delivered via the platform's publisher. Members could unsubscribe directly from receiving promotional emails by clicking the unsubscribe link at the bottom of every promotional email, as seen in the email in question (PM-GB-BLM-EML-220011). Unsubscribe requests are processed, recorded in the platform publishers database and applied to program lists systematically within 24 hours.

GlaxoSmithKline therefore believed that the consent conditions for recipients of this promotional email met the requirements of Clause 15.5 of the 2021 Code.

**Ensuring the promotional email was only distributed to health professionals whose need for, or interest in, it could be reasonably assumed**

A condition of sending the triggered email to health professionals was the health professional accessing conditional content that would indicate an interest in a given topic. Regarding the sending of the email in question, this required the health professional to have clicked on and opened, within the previous 24-48 hours, a link to an article on the platform's website where the lead condition was multiple myeloma, or an article containing a substantial amount of multiple myeloma content. All tagging is validated by a member of its editorial team.

When a health professional registered for the platform, they were directed to tick a box to agree to its privacy policy, in which the following statement was included: *'We may personalize the Services, including the advertising you see within the [platform] Network, on third party websites and in our email communications, based on information included in your Member Profile. For example, a user who [*the platform's publisher] *believes is a cardiologist or who has browsed cardiology content with the [platform] Network may be served an advertisement promoting a particular cardiac product within the [platform] Network, on third party websites and/or within an email that a user who [the platform's publisher] believes is a neurologist or has not browsed cardiology content will not see'.*

The platform's publisher have confirmed that there were no errors in the set-up or delivery of this campaign, and therefore email recipients had viewed an article tagged to multiple myeloma.

GlaxoSmithKline therefore believed it was reasonable to assume the health professionals receiving the triggered email had a need for or an interest in multiple myeloma, and therefore that this met the requirements of Clause 5.6 of the 2021 Code.

**Balance of content within promotional email PM-GB-BLM-EML-220011**

GlaxoSmithKline stated Blenrep was indicated as monotherapy for the treatment of multiple myeloma in adult patients, who had received at least four prior therapies and whose disease was refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who had demonstrated disease progression on the last therapy.

The promotional email contained data from the Phase II pivotal DREAMM-2 study (NCT03525678) and provided a balanced overview of both efficacy and safety data. The data

was consistent with the approved indication and Summary of Product Characteristics (SmPC) for Blenrep. The promotional email was reviewed and certified, and the final form was inspected and approved on 1 December 2022 by a registered pharmacist (qualifications: Mpharm).

GlaxoSmithKline submitted the complainant had stated that the 'material was imbalanced as it does not make mention of the recent failure of this product in a Phase III confirmatory trial which led to its withdrawal from several international markets'.

The Phase III trial referred to by the complainant is the DREAMM-3 study (NCT04162210), a head-to- head superiority study for Blenrep, which did not meet its primary endpoint of progression-free survival (PFS) in patients with relapsed/refractory multiple myeloma in monotherapy relative to an active control (pomalidomide in combination with low dose dexamethasone).

The DREAMM-3 study was investigational in nature in a different line of therapy and population (i.e. unlicensed indication) compared to DREAMM-2 so it would be entirely inappropriate to include any reference to it within a promotional email relating to a separate, licensed indication:

- DREAMM-2/BLENREP GB marketing authorisation:
  Patients must have received 'at least four prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody' (copy provided).

- DREAMM-3:
  Patients must have received 'at least two prior lines of anti-myeloma treatments, including at least two consecutive cycles of both lenalidomide and a proteasome inhibitor' (copy provided).

Topline data from the DREAMM-3 study were announced in a press release on 7 November 2022 (copy provided). While the study did not meet its primary endpoint, patients in the DREAMM-3 trial who responded to treatment with Blenrep achieved deep and durable responses. The observed median progression free survival (PFS) was longer for Blenrep than for Pomalidomide+Dexamethasone (11.2 vs 7 months) and importantly safety data was consistent with previous trials. GlaxoSmithKline remained confident in Blenrep and its value as a treatment option for patients with multiple myeloma as per the approved indication.

Discussions with the health authorities were ongoing, and as of the date of the letter of response, Blenrep continued to be approved by the Medicines and Healthcare products Regulatory Authority (MHRA) and European Medicines Agency (EMA) for the following indication:

- Blenrep is indicated as monotherapy for the treatment of multiple myeloma in adult patients, who have received at least four prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy.

Therefore, GlaxoSmithKline believed that the content of the promotional email in question was accurate, up-to-date, fair and balanced, and was consistent with the Blenrep Summary of Product Characteristics (SmPC). Accordingly, it met the requirements of Clause 6.1 of the ABPI Code.

**Conclusion**

In closing, GlaxoSmithKline stated their position was that the content and distribution of the Blenrep promotional email were consistent with the requirements of Clauses 5.6, 6.1 and 15.5 of the 2021 Code, and GlaxoSmithKline denied breaches of these clauses. Consequently, high standards had been maintained and GlaxoSmithKline refuted a breach of Clause 5.1 of the 2021 ABPI Code.

**Request for Further Information**

In response to a request for further information from the Panel in relation to the consent of the particular complainant, GlaxoSmithKline submitted that they had worked with the platform's publisher and obtained the specific details to demonstrate the complainant had signed up to receive promotional emails as stated in their letter of response and provided copies of screenshots obtained from the platform's publisher, including how and when the complainant signed up, whether the complainant had unsubscribed at any point, and any additional details regarding the complainant's consent.

GlaxoSmithKline submitted the information provided by the platform's publisher, confirming the complainant's consent to receive promotional emails from pharmaceutical companies at the time of receipt of the email in question. Based on the complainant's haematology/oncology speciality and engagement with multiple myeloma content, in the 2 months leading up to the triggered email, it was reasonable to assume that they had a legitimate need or interest in receiving information about Multiple Myeloma treatments.

Therefore, GlaxoSmithKline's position was that it had complied with the requirements of the Code and denied breaches of Clauses 5.1, 5.6 and 15.5 of the 2021 Code, with the reasoning as detailed below and within GlaxoSmithKline's initial letter of response. In GlaxoSmithKline's initial response letter a breach of Clause 6.1 of the 2021 Code was also denied, although further detail was not required for the purposes of the letter providing further information.

**Confirmation of consent to receive promotional emails**

GlaxoSmithKline submitted the promotional email in question was used as part of a 3rd party email program which is part of the platform publisher's health professional network and reiterated the information regarding the platform and the registration process to consent to receive promotional emails, which was set out in the original response.

The platform's publisher had confirmed that the user profile for the complainant was created on 2 August 2020. At the point of registration, the complainant actively ticked the box to opt in to receive promotional emails (copy provided).

All emails sent signpost users to unsubscribe options, and this could be seen clearly at the bottom of the email in question (copy provided). However, the complainant had, at no point, unsubscribed from receiving promotional emails. The screenshots from the platform publisher's user database showed that as of 18 November 2023 (date of the complainant's last visit to the website), their account settings remained opted in for receiving promotional emails (copy provided).

As the complainant's consent to receive promotional emails had been active for the full duration, since initially registering for an account on 2 August 2020, to their last visit on 18 November 2023, it therefore followed that active consent to receive promotional emails was in place in December 2022, at the time of receipt of the email in question.

GlaxoSmithKline therefore believed that the consent conditions for the complainant to receive promotional emails met the requirements of Clause 15.5 of the 2021 Code.

**Ensuring the promotional email was only distributed to health professionals whose need for, or interest in it could be reasonably assumed**

GlaxoSmithKline submitted that for a health professional to receive a triggered email as part of this program the following criteria were all required to be met:

- The health professional must have provided an email address and consented to receive promotional information from pharmaceutical companies via the platform's publisher, by proactively opting in to 'receive relevant information from industry' during the platform registration process.
- The health professional must be logged into the platform website.
- The health professional must have clicked on, and opened at least one page on the platform website, tagged with multiple myeloma as the lead condition, or with a substantial amount of multiple myeloma content within the previous 24 to 48 hours. All tagging was validated by a member of its editorial team.

The complainant received the triggered email because they fulfilled all 3 criteria. The complainant was registered on the platform as a physician with specialty in haematology/oncology. The platform publisher had confirmed that the complainant actively engaged with multiple pieces of content relating to the treatment of multiple myeloma in the period November/December 2022 whilst logged into the website (copy provided).

GlaxoSmithKline therefore believed it was reasonable to assume that the complainant had a legitimate need or interest in multiple myeloma treatments, and therefore that this met the requirements of Clause 5.6 of the 2021 Code.

**Conclusion**

In closing, GlaxoSmithKline's position was that the content and distribution of the Blenrep promotional email, and specifically the distribution of the email to the complainant, were consistent with the requirements of Clauses 5.6, 6.1 and 15.5 of the 2021 Code, and GlaxoSmithKline denied breaches of these clauses. Consequently, high standards had been maintained and GlaxoSmithKline refuted a breach of Clause 5.1 of the 2021 ABPI Code.

**PANEL RULING**

The Panel noted the complainant had received an email on 27 December 2022 promoting a GlaxoSmithKline medicine which was allegedly unsolicited; the subject line of the email read: 'GSK: Rethink your treatment strategy for RRMM patients (contains promotional content)'. The complainant submitted that they had never given consent to receive promotional material to the e-mail address nor did they treat patients with multiple myeloma. The complainant further alleged the material was imbalanced.

The Panel noted that normally the identity of the complainant was kept confidential and not disclosed to the respondent company unless the disclosure of their identity was necessary for the company to properly investigate the allegation. Given the nature of the allegation, the complainant agreed to provide the necessary permissions and waive their anonymity so that GlaxoSmithKline could identify their details to properly investigate the complaint.

Prior permission for promotional emails

In its initial response, GlaxoSmithKline provided a broad response in relation to the platform's publisher having adequate permissions but had not provided information regarding whether their investigation involved checking the data for the named health professional. Following a request for additional information, the Panel noted GlaxoSmithKline's submission that the platform's publisher had identified the user and confirmed that the complainant had and still was opted in to receive promotional emails; the user account was created in August 2020 and their last visit was during the month of GlaxoSmithKline's response to further information. GlaxoSmithKline submitted all emails clearly signposted users to the unsubscribe options at the bottom of the email in question and the complainant had, at no point, unsubscribed.

The Panel noted GlaxoSmithKline's submission that the promotional email in question was used as part of a third party email program. For a health professional to receive a triggered email as part of this program the following criteria were all required to be met:

- The health professional must have provided an email address and consented to receive promotional information from pharmaceutical companies via the platform's publisher, by proactively opting in to 'receive relevant information from industry' during the platform's registration process.
- The health professional must be logged into the platform's website.
- The health professional must have clicked on, and opened at least one page on the platform's website, tagged with multiple myeloma as the lead condition, or with a substantial amount of multiple myeloma content within the previous 24 to 48 hours. All tagging was validated by a member of the platform's publishers editorial team.

GlaxoSmithKline submitted that the complainant received the triggered email because they fulfilled all three criteria. GlaxoSmithKline submitted the complainant was registered as a physician under the specialty haematology/oncology and had actively engaged with multiple pieces of content relating to the treatment of multiple myeloma in the period November/December 2022, thus making them a legitimate recipient of the email in question.

It appeared to the Panel, noting GlaxoSmithKline's submission and on the evidence before it, that the complainant had provided prior permission to receive promotional emails and the Panel **ruled no breach of Clause 15.5 of the Code**. Additionally, noting the specialty under which the complainant had registered and their engagement with content, the Panel considered the complainant's interest in multiple myeloma could reasonably be assumed and therefore **ruled no breach of Clause 5.6 of the Code**. In this regard, the Panel noted it had no evidence that high standards had not been maintained and **no breach of Clause 5.1 was ruled** accordingly.

Balance of content within the promotional email

The Panel noted the content of the email at issue was headed 'BLENREP (belantamab mafodotin): Think BCMA, think BLENREP in relapsed and refractory multiple myeloma (RRMM)' and included, among other things, the attributes of BCMA that made it 'an ideal target in multiple

myeloma', a link to a mechanism of action video for BLENREP, and results of a Phase II clinical trial, DREAMM-2; DREAMM-2 was an open-label, two-arm, phase 2 clinical trial, in patients with triple-class refractory multiple myeloma.

The Panel noted the narrow complainant's allegation that the material was imbalanced as it did not make mention of the recent failure of this product in a Phase III confirmatory trial which led to its withdrawal from several international markets. In this regard, the Panel noted GlaxoSmithKline's submission that the Phase III trial referred to by the complainant was the DREAMM-3 study (NCT04162210), a head-to-head superiority study for BLENREP, which did not meet its primary endpoint of progression-free survival (PFS) in patients with relapsed/refractory multiple myeloma in monotherapy relative to an active control (pomalidomide in combination with low dose dexamethasone). GlaxoSmithKline submitted the DREAMM-3 study was investigational in nature in a different line of therapy and population (i.e. unlicensed indication) compared to DREAMM-2 so it would be entirely inappropriate to include any reference to it within a promotional email relating to a separate, licensed indication.

GlaxoSmithKline had further submitted that discussions with the health authorities were ongoing, and as of the date of their response, Blenrep continued to be approved by the MHRA and EMA for the following indication: 'Blenrep is indicated as monotherapy for the treatment of multiple myeloma in adult patients, who have received at least four prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy'; in this regard, the Panel noted the indication cited by GlaxoSmithKline in their response was identical to the indication cited in the promotional email.

The Panel noted that the Constitution and Procedure stated that the complainant had the burden of proving their complaint on the balance of probabilities. All complaints were judged on the evidence provided by both parties. The Panel, noting GlaxoSmithKline's submission, considered that the complainant had referred to data from the DREAMM-3 study, which was for a separate, licensed indication than that discussed in the promotional email at issue. Blenrep was licensed in Great Britain which permitted its sale or supply and, in this regard, appropriate promotion by GlaxoSmithKline was permitted. The Panel did not consider that the omission of results for the DREAMM-3 study, which was not in line with the licensed indication at the time of the complaint according to GlaxoSmithKline, rendered the email misleading and the Panel therefore ruled **no breach of Clause 6.1** of the Code. Noting its ruling of no breach and that the complainant had not established high standards had failed to be maintained, the Panel ruled **no breach of Clause 5.1** of the Code.

**Complaint received** **27 December 2022**

**Case completed** **5 January 2024**