

COMPLAINANT v GLAXOSMITHKLINE

Allegations about a Shingrix article in the Daily Mail

CASE SUMMARY

This case was in relation to a Shingrix article written by an independent health journalist and published in the Daily Mail online.

The Panel ruled no breach of the following Clauses of the 2021 Code as, in the Panel's view, although the sensationalist language in the Daily Mail article might encourage members of the public to ask their health professional to prescribe Shingrix, the Panel did not consider, on the evidence before it, that this was a consequence of the two press releases that GlaxoSmithKline had issued to business/financial journalists some months earlier, nor the information GlaxoSmithKline had provided reactively to the health journalist in question following their request for information. The Panel considered that the complainant had not established that GlaxoSmithKline had failed to maintain high standards:

No Breach of Clause 5.1	Requirement to maintain high standards at all times.
No Breach of Clause 26.1	Requirement to not advertise prescription only medicines to the public.
No Breach of Clause 26.2	Requirement that information about prescription only medicines which is made available to the public must be factual, balanced, must not raise unfounded hopes of successful treatment and must not encourage the public to ask their health professional to prescribe a specific prescription only medicine.

**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 from a contactable complainant, who described themselves as a member of the public, about GlaxoSmithKline.

COMPLAINT

The complainant stated that they wanted to know how an article in the Daily Mail was allowed to be in the public domain when it discussed the benefits of a prescription product and promoted a vaccination that was not on the NHS immunisation schedule (Shingrix) directly to consumers. A link to the article was provided by the complainant.

Following a request from the case preparation manager for declarations of interest, the complainant stated that they were employed by an organisation that was not a pharmaceutical company and that they saw the article as a member of the public and had a genuine interest in how the journalist was able to not only name the product in the UK media, but outline that the product was superior to the existing vaccine on the NHS immunisation schedule.

When writing to GlaxoSmithKline, the Authority asked it to consider the requirements of Clauses 5.1, 26.1 and 26.2 of the Code.

RESPONSE

GlaxoSmithKline stated that it took its obligations under the ABPI Code of Practice extremely seriously and was committed to following both the letter and spirit of the Code. GlaxoSmithKline confirmed it was not involved in initiating, authoring or sponsoring the article which was the subject of the complaint. Furthermore, neither GlaxoSmithKline (nor its third parties) had issued any proactive Shingrix or shingles related materials (including press releases and verbal or written briefings) or given any interviews about Shingrix or shingles to the Daily Mail journalist who authored the article, in the period leading up to its publication. GlaxoSmithKline stated it had been conservative and diligent in its approach to this time-period and had looked back as far as the beginning of 2021.

Background

Reactive communication with the author of the Daily Mail article:

GlaxoSmithKline submitted that for completeness and transparency it was providing a timeline of relevant reactive interactions between GlaxoSmithKline and the author of the article regarding Shingrix or shingles as below:

31 January 2022 – GlaxoSmithKline UK received an unsolicited request for an interview with a GlaxoSmithKline spokesperson about Shingrix from the author of the article. They advised that they were writing a story on shingles and its treatments [sic] including Shingrix and requested to speak with someone at GlaxoSmithKline about Shingrix, the science and its rollout.

1 February 2022 – The unsolicited request for an interview was passed internally within GlaxoSmithKline who then asked the journalist for further clarity regarding the areas they wished to discuss at interview. At this point, the journalist also asked for GlaxoSmithKline's help sourcing a patient who had experienced shingles to interview.

2 February 2022 – The journalist confirmed the following topics were of interest to them: the science behind Shingrix, the vaccine's effectiveness, how Shingrix compared to competitor products, the impact of Shingrix vaccine roll-out in other countries and the likely impact of its roll-out in the UK, the impact of Shingrix and shingles on patients and when NHS patients could expect to get Shingrix.

3-10 February 2022 – The unsolicited request for an interview with a GlaxoSmithKline spokesperson was discussed internally and there were further clarifying communications. On 10 February, the request for an interview was subsequently declined because of concerns regarding the risk of promoting a prescription only medicine to the public via the

consumer media. This reactive email was examined by a senior person within GlaxoSmithKline UK prior to sending to ensure it did not contravene the Code.

GlaxoSmithKline responded to the unsolicited enquiries about the Shingrix roll-out in the UK and when NHS patients could expect to get Shingrix (received on 31 January and 2 February, respectively) via email. GlaxoSmithKline submitted that it provided the following factual, balanced and non-promotional information:

‘...we can confirm that Shingrix is available in the UK. It is currently available via the NHS for 70-79 year-old immunocompromised patients and we’re also in regular contact with government regarding future wider availability in the UK. Your question regarding timelines might be best directed to the UK Government (Department for Health & Social Care) and/or JCVI.’

GlaxoSmithKline’s response also included a hyperlink to an NHS webpage entitled “Who can have the shingles vaccine?”, which it submitted was a credible, independent source of information about the UK Shingles National Immunisation Programme.

Regarding the unsolicited enquiry about a shingles patient case study (received on 2 February), GlaxoSmithKline suggested that the journalist might wish to contact a named patient organisation. GlaxoSmithKline’s response included a hyperlink to the patient organisation’s webpage and the email address of this organisation’s Director. The patient organisation webpage provided general information for patients on shingles, its cause, signs and symptoms, risk factors, complications, treatment and prevention.

Communication with Daily Mail business/financial journalists:

GlaxoSmithKline submitted that the only other correspondence with the Daily Mail about Shingrix since the beginning of 2021 related to two GlaxoSmithKline press releases which were circulated to business/financial journalists only, including those at the Daily Mail.

The press release issued on 26 July 2021 announced the FDA’s [Food and Drug Administration] approval of Shingrix for the prevention of shingles in adults 18 years and older who were, or who would be, at risk of shingles due to immunodeficiency or immunosuppression caused by known disease or therapy. In terms of its business significance, the FDA’s approval of this new indication for Shingrix, within the major US market, was a key clinical milestone, significantly expanding the number of people who could potentially benefit from protection against shingles with Shingrix. Its approval also represented the first shingles vaccine specifically indicated for use in this immunocompromised population, addressing an unmet need.

The other press release, dated 20 October 2021, announced the US Centers for Disease Control and Prevention’s Advisory Committee on Immunisation Practices’ (ACIP) decision to recommend Shingrix for immunocompromised adults aged 19 and above. In terms of its business significance, ACIP’s decision to recommend Shingrix for immunocompromised adults aged 19 and above was a critical step to ensuring that patients within the major US market could obtain access to Shingrix.

GlaxoSmithKline confirmed that it did not send either press release to the author of the article, who was a health journalist; it was only sent to business/financial journalists. It was noteworthy that no related articles appeared in the Daily Mail following the issue of these business press

releases. There was also a significant time lag (7 and 4 months, respectively) between their issue to business/financial journalists and the publication of the article in question. Furthermore, the content of the article was considerably different from that of the press releases and the article did not mention either the FDA's approval or ACIP's recommendation of Shingrix for this new population.

Clauses 26.1 and 26.2

GlaxoSmithKline submitted that Clause 26.1 stated that prescription only medicines must not be advertised to the public whilst Clause 26.2 allows for the provision of non-promotional information about prescription only medicines to the public either in response to a direct enquiry from an individual, including enquiries from journalists, or by dissemination of such information via press conferences, press announcements, television and radio reports, public relations activities etc. The supplementary information to this clause clarified that 'Any information must observe the principles set out in this clause; that is, it should be factual, balanced and must not encourage members of the public to ask their doctors or other prescribers to prescribe a specific prescription only medicine. It must not constitute the advertising of prescription only medicines to the public prohibited under Clause 26.1'. The supplementary information also stated that reactive information 'must be limited to that information necessary to respond to the request'.

GlaxoSmithKline stated that the supplementary information to Clause 26.2 also provided clarity regarding 'information made available by pharmaceutical companies in order to inform shareholders, the Stock Exchange and the like by way of annual reports and announcements'. Whilst such information 'may relate to both existing medicines and those not yet marketed', it must be 'non-promotional, accurate, presented in a factual and balanced way and not misleading' and 'take into account the information needs of the target audience'. It further clarified that 'business press releases should identify the business importance of the information and should only be aimed at the intended financial and investment audience'.

GlaxoSmithKline submitted that the information it provided to the author of the article was factual, balanced, non-promotional and in response to a legitimate unsolicited request for information. GlaxoSmithKline's response was limited to that required to answer questions raised by the author and GlaxoSmithKline was satisfied that its content would not encourage members of the public to ask for a specific medicine, nor would it constitute the advertising of prescription only medicines to the public.

GlaxoSmithKline submitted that in terms of the business press releases, in compliance with the Code, these were issued to business/financial journalists only; and GlaxoSmithKline confirmed that it did not send them to the author of the article, a health journalist. The contents of both press releases were non-promotional and presented in a factual and balanced way and the business importance of the FDA's approval and ACIP's recommendation of Shingrix, within the major US market, would be clear to the intended business/financial journalist audience. GlaxoSmithKline confirmed that no related articles appeared in the Daily Mail following the issue of these press releases. In addition, the article which was the subject of this complaint was published many months after the issue of the press releases to business/financial journalists at the Daily Mail and did not mention either of the milestones which were the focus of these press releases.

GlaxoSmithKline stated that it was confident that its activities were fully compliant with the Code and that high standards had been maintained; GlaxoSmithKline strongly refuted breaches of Clauses 26.1 and 26.2.

Clause 5.1

GlaxoSmithKline submitted that Clause 5.1 required companies to maintain high standards at all times and that no proactive information was provided to the author of the article; GlaxoSmithKline responded to a legitimate, unsolicited request for information and provided the journalist with a factual, balanced, non-promotional response that was fully compliant with the Code. Additionally, the matter was only dealt with by appropriately trained and qualified staff. GlaxoSmithKline contended it had maintained high standards and therefore refuted any breach of Clause 5.1.

With regard to the other information requested, as detailed above, GlaxoSmithKline could confirm there were no press releases or verbal/written briefings about Shingrix or shingles issued to the author of the article in the period leading up to the article's publication – GlaxoSmithKline submitted it had diligently reviewed as far back as the start of 2021. The only other correspondence with the Daily Mail about Shingrix related to two GlaxoSmithKline business press releases which were circulated to business/financial journalists as detailed previously. GlaxoSmithKline had checked, and could confirm, that it did not send either press release to the author of the article, a health journalist.

Conclusion

In closing, GlaxoSmithKline confirmed that it was not involved in the article itself. GlaxoSmithKline's interactions with the Daily Mail journalist, who authored the article about Shingrix and shingles in the period leading up to the article's publication, was strictly limited to the provision of factual, balanced and non-promotional information in response to unsolicited enquires. GlaxoSmithKline was confident that its activities were fully compliant with the Code and GlaxoSmithKline strongly refuted breaches of Clauses 26.1, 26.2 and 5.1.

PANEL RULING

The Panel noted that the complaint related to an article titled, "Game-changing" vaccine that can cut the risk of shingles by more than 90 per cent is set to be offered to all eligible over-70s in the UK', written by a journalist for the Mail on Sunday and published in the Daily Mail Online on 19 February 2022.

The Panel noted that Clause 26.1 stated, among other things, that prescription only medicines must not be advertised to the public. Clause 26.2 stated, among other things, that information about prescription only medicines which is made available to the public either directly or indirectly must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading with respect to the safety of the product. Statements must not be made for the purpose of encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine.

The supplementary information to Clause 26.2 stated, among other things, that this clause allowed for the provision of non-promotional information about prescription only medicines to the public either in response to a direct enquiry from an individual, including enquiries from

journalists, or by dissemination of such information via press conferences and press announcements etc.

The Panel noted that Shingrix was a prescription only medicine and regardless of its status within the NHS immunisation schedule, it must not be advertised to the public. This prohibition did not apply to vaccination campaigns carried out by companies and approved by the health ministers. The Daily Mail article at issue did not appear to be part of such a campaign.

The Panel noted that when complaints were received about information that an independent journalist had published in the press, its rulings were made upon the material released by the company that might have prompted the article, and not the article itself. The tone, language and content of any relevant press release(s) provided by the company, and any interactions the company had with the journalist, would be important considerations in this regard.

The Panel noted GlaxoSmithKline's submission that it had issued two press releases about Shingrix, circulated to business/financial journalists only, including those at the Daily Mail, in July and October 2021.

The Panel noted that the first press release, issued by GlaxoSmithKline on 26 July 2021, titled 'Shingrix approved in the US for prevention of shingles in immunocompromised adults' announced the FDA's approval of Shingrix for the prevention of shingles in adults 18 years and older who were, or who would be, at increased risk of shingles due to immunodeficiency or immunosuppression caused by known disease or therapy.

The second press release, dated 20 October 2021, titled 'US Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices votes unanimously to recommend Shingrix for immunocompromised adults aged 19 and up' announced the US Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunisation Practices (ACIP) decision.

Both press releases were issued from Philadelphia and London and stated they were for media and investors only.

According to GlaxoSmithKline, the two press releases were not sent to the author of the article at issue who was a health journalist; the two press releases were circulated to business/financial journalists only. Furthermore, there was a time lag of 7 and 4 months, respectively, between the issue of each press release and the publication of the Daily Mail article in question.

The Panel noted that whilst the Daily Mail article made some reference to the US, it made no specific reference to the FDA approval or ACIP which were the focus of the two press releases. Furthermore, the language and tone of the press releases were very different to the article. The Panel noted that the article contained statements such as: 'Game-changing'/'Game changer'; 'far more successful at preventing the painful viral skin condition than the vaccine currently offered on the NHS'; 'the news will come as a relief to the millions of Britons at risk ...' which were not statements from either of the press releases.

Noting the differences in tone, language and content between the press releases and the Daily Mail article at issue and considering the time delay between the issuing of the press releases

and the publication of the article, the Panel did not consider that the article had been written as a consequence of the two GlaxoSmithKline press releases described above.

The Panel further noted GlaxoSmithKline's submission that it had interacted with the author of the article in the period leading up to its publication, on a reactive basis only. According to GlaxoSmithKline, an unsolicited request for information from the journalist was received on 31 January 2022 and, following a number of clarifying communications, GlaxoSmithKline responded by email on 10 February, including declining the journalist's request for an interview.

The Panel noted GlaxoSmithKline's email response of 10 February stated that the company could not 'speak about/promote our products to the public. This means any GSK contribution to an article which talks about our vaccine is a challenge for us to respond to'. The email further stated:

'That said, for your background info and in response to your original questions, we can confirm that Shingrix is available in the UK. It is currently available via the NHS for 70-79 year-old immunocompromised patients and we're also in regular contact with government regarding future wider availability in the UK. Your question regarding timelines might be best directed to the UK Government (Department for Health & Social Care) and/or JCVI. Sorry we couldn't provide more of a comprehensive response on this occasion, but I hope the above helps in some way. We look forward to reading the final article.'

The email included a hyperlink to an NHS webpage titled 'Who can have the shingles vaccine?' which GlaxoSmithKline submitted was a credible, independent source of information about the UK Shingles National Immunisation Programme.

The Panel noted GlaxoSmithKline's submission that there was also an unsolicited enquiry from the journalist on 2 February 2022 about a shingles patient case study. GlaxoSmithKline stated that it responded to the journalist by suggesting they contact a named patient organisation and provided the journalist with a hyperlink to this organisation's webpage and the email address of its Director. The Panel noted that the patient organisation webpage screenshot provided by GlaxoSmithKline provided general information for patients with shingles.

The supplementary information to Clause 26.2 included that reactive information can be supplied to the public (including journalists) in response to a direct request but must be limited to that information necessary to respond to the request.

The Panel did not have visibility of the journalist's original enquiries; GlaxoSmithKline had only provided its email response of 10 February and a summary of what the journalist had requested over a number of days.

The Panel was not an investigatory body; the complainant had the burden of proving their complaint on the balance of probabilities.

Whilst the Panel had some concerns about the tone of the email and the reference to future wider availability in the UK, it appeared that there had been a specific question from the journalist about timelines given the response stated, 'Your question regarding timelines might best be directed to the UK Government (Department for Health & Social Care) and/or JCVI'. Whilst the Panel did not have visibility of all correspondence between GlaxoSmithKline and the

journalist during this time, there was no evidence before it that GlaxoSmithKline's response went beyond answering that which was specifically requested by the journalist.

The language in the email from GlaxoSmithKline of 10 February did not use the sensationalist language in the Daily Mail article such as 'game-changing' nor did it give efficacy results or make any comparison with another shingles vaccine; the latter of which appeared to be of particular concern to the complainant.

In the Panel's view, although the language in the Daily Mail article written by an independent journalist might encourage members of the public to ask their health professional to prescribe Shingrix, the Panel did not consider, on the evidence before it, that this was a consequence of the information GlaxoSmithKline had provided to the journalist in question. The Panel therefore ruled **no breach of Clauses 26.1 and 26.2.**

Given the rulings above, the Panel considered that the complainant had not established that GlaxoSmithKline had failed to maintain high standards and therefore the Panel ruled **no breach of Clause 5.1.**

Complaint received 7 September 2022

Case completed 13 November 2023