CASE AUTH/3866/12/23

COMPLAINANT v MERCK SERONO

Allegations regarding Merck promotional emails

CASE SUMMARY

This case was in relation to a number of Merck Serono emails sent by a third-party medical publisher which were promotional in nature.

The outcome under the 2021 Code was:

Breach of Clause 5.1	**Failing to maintain high standards**
Breaches of Clause 15.6 (x5)	**Disguising promotional material**
Breach of Clause 16.3	**Restraint to be exercised on the frequency of distribution and on the volume of promotional material distributed**

No Breach of Clause 5.1	**Requirement to maintain high standards**
No Breach of Clause 5.5	**Requirement to be sufficiently clear as to the company's role and involvement**
No Breach of Clause 5.6	**Requirement for material to only be provided or made available to those groups of people whose need or interest in it can be reasonably assumed. Material should be tailored to the audience to whom it is directed.**
No Breach of Clause 15.5	**Requirement that the telephone, text messages, email, faxes, automated calling systems, and other digital communications must not be used for promotional purposes, except with the prior permission of the recipient**

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 health professional about Merck Serono Limited.

COMPLAINT

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

> "Dear PMCPA, I would like to make a complaint about a number of emails I am getting from [third-party medical publisher] which is paid for by Merck to promote their medicine – Bavencio. Since the 26th of September 2023, they have been sending me an email on average every 4 days about this medicine and it's getting irritating. Each email comes from an email address which suggests the content to be non promotional in content and the subject line also does not suggest any promotional intent in the email. The emails seem to rotate between a few main topics to attract readers to open it: • Explore efficacy data for a treatment in mUC [metatstatic urothelial cell carcinoma] • Manageable tolerability in mCU [mUC]• Guidelines recommendations in mUC • Data from the JAVELLIN 100 study. Each email content then has a link to open which leads to a promotional website from Merck on Bavencio. I counted at least 21 emails which did this and its only after I opened the email that I realised I fell for it again. The fact that the emails have a job bag which I see often in leaflets, means Merck must know how many times this email will be sent. Why can't they state in the email address or subject line that this email will promote their medicine before I open it? It's a cheap ploy to pay [third-party medical publisher] to use their address, trying to add an air of science to this spamming technique. And how do I unsubscribe to getting these every 4 days whilst not losing out on breaking news which would be worth reading? Pharmaceutical companies should be more transparent in their advertisements and make it clear from the outset. They should also not spam me with an email every 4 days. I hope you can stop this."

When writing to Merck Serono, the PMCPA asked it to consider the requirements of Clauses 5.1, 5.5, 5.6, 15.5, 15.6 and 16.3 of the 2021 Code.

MERCK SERONO'S RESPONSE

The response from Merck Serono is reproduced below:

> "Thank you for your letter dated 20 December 2023, concerning alleged breaches of the ABPI's Code of Practice for the Pharmaceutical Industry (the '**Code**'). Merck Serono Limited ('**Merck**') seeks to both fully comply with and embody the Code, and we are disappointed that we have received a complaint regarding a series of promotional emails related to our product Bavencio® (avelumab) (the '**Complaint**').
>
> The complainant alleges a number of issues, namely: (i) since 26 September, the complainant received an email roughly every four (4) days; (ii) the emails appear to come from an educational email address, but contain or link to promotional content; (iii) there is no indication that content is promotional until a link is accessed, taking the recipient to a promotional website for Bavencio; (iv) they received at least 21 emails during this the period from September to December 2023; (v) there was no statement of the email being promotional until it was opened; and (vi) the unsubscribe details were not clear.
>
> As requested in your letter, we have taken into consideration the following clauses of the Code:- 5.1 – Maintaining High Standards; 5.5 – Material must state the role of the pharmaceutical company; 5.6 – Material must only be provided to those whose need or interest in it can be reasonably presumed and should be tailored to the audience; 15.5 – Digital communications should not be used for promotional materials unless there is

prior permission of the recipient; 15.6 – Promotional material and activities must not be disguised; and 16.3 – Restraint must be exercised on the frequency of distribution and volume of promotional material distributed.

[Description of requested materials provided]

Background

Bavencio is indicated as a monotherapy for first-line maintenance treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC) who are progression-free following platinum-based chemotherapy. The data to support this were from the Javelin Bladder 100 study, the results of which were first presented at the American Society of Clinical Oncology meeting in June 2020 and simultaneously published in the New England Journal of Medicine. NICE [National Institute for Health and Care Excellence] published its decision to recommend Bavencio as a treatment option in urothelial cell carcinoma (UC, often referred to as bladder cancer) in line with the licensed indication for patients in England & Wales in May 2022. By this time, European and International guidelines had already made Bavencio maintenance treatment the standard of care for advanced or metastatic UC patients who did not progress after treatment with a platinum-containing regimen. The pathway for referral and treatment of patients is complex and involves many stakeholders and research shows that many patients with advanced or metastatic bladder cancer are not referred from the care of urologists to oncologists. The oncologists who lead treatment decisions also treat many other GU cancers including renal cell cancer (RCC). Even after referral, case discussions at MDT [multi-disciplinary team] meetings often do not evaluate the suitability of patients for maintenance therapy with avelumab, which is why this campaign was aimed at a wide range of multi-disciplinary specialists, to educate and inform them of the latest evidence and treatment guidelines.

1. Appropriate consent and Merck's status of involvement

Merck entered into an agreement with [Third-party medical publisher] to provide the latest information relating to the Javelin Bladder 100 study to interested customers, which was intended to inform accurate and safe prescribing of Bavencio in relevant patients (the '**Campaign**'). The Campaign was entered into in good faith to provide this valuable information only to appropriate and interested healthcare professionals, to communicate the latest data that was still emerging from the study and how these data could further impact decision making to ensure that HCPs could make informed prescribing decisions based on the latest evidence and international guidelines. The Scope of Work is included in *Attachment 3*, with a project summary and outcomes provided in *Attachment 4.*

[Third-party medical publisher] was chosen as a partner as they had access to a large database of customers which totalled 5,435 unique users in the UK who had an interest in the topics of the Campaign. [Third-party medical publisher] is ranked among the leading medical education companies by HCPs. This target list and topics for the Campaign included oncologists, nurses & surgeons interested in renal or bladder cancer or have consumed content on those topics, as well as consultant urologists or urology nurses who were interest in bladder cancer or have consumed content on those topics, and hospital pharmacists. The permissions to receive third

party digital communications are the intellectual property of [Third-party medical publisher], not those of Merck, and the list has not been shared with Merck due to GDPR [General Data Protection Regulations] . Notwithstanding, Merck has sought to utilise such information on the premise that [Third-party medical publisher] have obtained appropriate and lawful consent (and this is contractually stated), and that those people who have opted in to receive digital communications from [Third-party medical publisher] have done so willingly, in line with a communication preference and topics of interest. Further details of the subscription policy are provided in [an attachment].

Furthermore, regarding Merck's stated involvement in the Campaign, it is evident that the information was promotional from the outset, as is clearly stated on the example provided by the complainant. The Campaign comprised of a series of digital communications and targeted advertising, including email. Merck's use of digital media in this context is in line with prior permission of the complainant. The complainant has provided evidence of all four different emails with unique job codes: (i) UI-AVE-00125, (ii) UI-AVE-00131, (iii) UI-AVE-00129 and (iv) UK-AVE-00134. Each has a date of preparation of July 2023 and certificates and content for each of the jobs is provided [reference to attachments]. The emails were used in the period from September to December 2023. In each of the examples provided by the complainant, the text above clearly states this is a '[p]*romotional advertisement from Merck for UK Healthcare Professionals*.' In addition, at the bottom of each email is a statement that *'[t]he information contained in this email is brought to you by a third-party sponsor. This promotional communication is provided by [Third-party medical publisher] Professional Spotlight [Third-party medical publisher] LLC., who does not endorse or is responsible for the accuracy of the content.'* These multiple statements make it clear that the intent of the email is signposted as promotional, and Merck's involvement is also clearly stated.

Accordingly, Merck does not believe there is a breach of either Clauses 5.5 or 15.5 of the Code for the reasons set out above.

2. Disguised promotion and appropriate content

The complainant goes on to allege that *'[e]ach email comes from an email address which suggests the content to be non-promotional in content and the subject line also does not suggest any promotional intent in the email.'* However, the Complaint's evidence – the email address from which content was sent is from <[**Third-party medical publisher] Professional Spotlight**> Spotlight@mail.[third-party medical publisher]professional.com; this is a general email list that [Third-party medical publisher] use to send out email communication to those HCPs who have registered to receive communication from them as well as from industry partners. In each of the four different types of email that were sent by [Third-party medical publisher] as part of the Campaign, the complainant has provided evidence that clearly shows that under the main title or heading on the email, the first statement is that this is *'Information from Industry'*, clearly indicating that the communication is from a pharmaceutical company, Merck in this instance.

From reviewing the other topics the complainant provided, it is also clear that the [Third-party medical publisher] Professional Spotlight email address is used to

distribute disease educational content from Third-party medical publisher, as well as industry content that can be both promotional or educational. The Campaign emails clearly stated that they are promotional. There is an example provided by the complainant which contains content relating to Non-Small Cell Lung Cancer from another pharmaceutical company [named pharmaceutical company], which clearly states that the content is only for HCPs' medical education. The complainant also alleges that the subject line does not indicate any promotional content. However, the subject line merely shows the recipient what is the topic covered in the main body of the email, which is the case here. If the title is of interest to the recipient, it would be expected that they would open the email and the promotional nature of the email is then clearly stated to the recipient. We also repeat the argument put forward in (i) above, regarding appropriate identification of content: there are numerous sign-postings that the material was promotional, and Merck's involvement is clearly stated.

The contract between Merck and [Third-party medical publisher], included a target of 1,090 click-throughs for the Campaign, ' (including email and advertising), with the click-throughs sending the recipient to a different section on the promotional website for Bavencio. Each section includes more in-depth information on the topics that were outlined in the content of the email itself. If the recipient of the email chooses to click through to read more, there is a clear statement that the recipient is clicking to an external link. When any of the links are clicked, the landing page seeks confirmation that they are a UK based HCP and displays the statement that the website is a Merck Immuno-Oncology website that is intended for HCPs containing educational and promotional materials relating to Merck products (see *Attachment 14*). If the recipient sees this welcome message each time they click through, it may appear that the content would look similar; however, it is mandatory for the opening page to check the validity of the viewer as an HCP before additional content is provided.

For the reasons set out above, Merck refutes any breach of Clauses 5.6 and 15.6 of the Code – the content of the email was clearly promotional, not disguised in any way and relevant for the target audience.

3. Frequency of delivery

There were four separate emails used as part of the campaign, with unique job codes and subjects: -

(i) UI-AVE-00125 – Javelin Bladder 100 trial: can mOS be improved in locally advanced or metastatic urothelial carcinoma?. The click through from this email links through to the efficacy section of the website [link provided]

(ii) UI-AVE-00131 – See what UK and European Guidelines recommend in locally advanced or metastatic urothelial carcinoma. The click through from this email links through to the Guidelines section of the website [link provided]

(iii) UI-AVE-00129 – Explore the safety and tolerability a first lime maintenance treatment in locally advanced or metastatic urothelial carcinoma. The click

through from this email linked through to the safety profile page of the website [link provided]

(iv) UK-AVE-00134 – Explore efficacy data of a first line maintenance treatment option in locally advanced or metastatic urothelial carcinoma. The click through from this email links through to the efficacy section of the website [link provided]

The Campaign was planned to run for six months to generate a total of 1,090 click-throughs from the various digital channels, of which the emails were expected to generate about 40% of the total click-throughs. There were four emails in total, as outlined by the complainant, which were on different topics and were designed such that the recipient would be taken to the relevant part of the website, although as already described, the first page that would be visible to the recipient on clicking through would be the pop-up to ask whether the recipient was an HCP or not.

From the data provided by [Third-party medical publisher], on pacing and frequency in Attachment 4, the frequency of the emails was flexible and determined by the click-through numbers. To achieve the 'BrandDirect Guarantee' of the target click-throughs, [Third-party medical publisher] adjust the frequency of emails up to a maximum frequency of one email every 16 days for each of the four emails, which is a threshold that [Third-party medical publisher] has determined is the limit of acceptable frequency of communication. This means that in each 16-day period a recipient received each of the four emails, which is in line with the frequency that the complainant received. This is standard [Third-party medical publisher] practice and Merck was neither involved nor had any visibility of this decision, as is outlined in Attachment 4. To further monitor whether the frequency is acceptable to the recipients, [named medical publisher] tracks unsubscribe rates, which for the Campaign were low at 0.03%, suggesting that most recipients were comfortable with the frequency of e-mail communication.

Full details of the dates and subjects of the emails that were sent are provided in the table in [named attachment], together with monthly frequency rates and unsubscribe rates.

Merck believes that there is no breach of Clause 16.3 of the Code as [Third-party medical publisher's] actions amount to standard practice. Furthermore, due to this being established and long-standing practice, there cannot be a breach of clause 5.1 of the Code.

4. Subscription

Finally, the complainant also raised the issue of not being able to unsubscribe without losing relevant important updates. In all the evidence provided by the complainant, there were two unsubscribe links that were signposted, as seen below, highlighted in yellow in Attachment 16. These links allow the recipient to unsubscribe from either 'these' or 'all' sponsored communications, so the options to unsubscribe were clear and present. If the recipient has any queries as to why they receive emails or any questions on how to unsubscribe that is matter for [Third-party medical publisher] and links to their terms of use and customer service team are below these. [Third-party medical publisher] has provided further clarification of

their subscription rules including how to unsubscribe. We therefore believe that there is no breach of Clause 5.1 and high standards have been maintained.

Summary and Conclusion

Merck would like to reassure you that we take compliance with the Code extremely seriously and have thoroughly investigated the Complaint. We believe that the Campaign had clear promotional intent, was targeted at appropriate audience who would be relevant and interested in the content and that the promotional intent was clearly and transparently communicated. The work has been conducted in partnership with an experienced and trusted provider that is a leader in this type of communication in the UK. We believe that Merck and [Third-party medical publisher] have adhered to both the letter and the spirit of the Code and that high standards have been maintained throughout this project.

We remain at your disposal, should any additional information be required."

In response to a request from the Panel for a copy of the landing page Merck stated that it was pasted into its original response letter.

PANEL RULING

The Panel noted that this complaint concerned fourteen promotional emails (of which three emails were described as "hand-picked" invitations for the complainant and including one email dated 31 October 2023 of which the Panel did not have a complete copy) sent repeatedly to a health professional from a third-party medical publisher relating to Bavencio (avelumab), a Merck Serono medication.

The Panel further noted that the PMCPA was dealing with a series of cases that involved the medical publisher in question and various companies. The allegations and evidence provided in each case differed and thus consequentially the rulings. Each case was considered independently on the evidence before each Panel.

The complainant stated that between 26 September 2023 and December 2023, they had received emails, on average every four days with differing subject lines to attract readers to open it; each email then contained a link which led the user to different sections of a Merck Serono promotional website for Bavencio. The Panel noted that the earliest complete email provided by the complainant was dated 4 November 2023

The Panel noted that the emails in question were sent from the following email address: Spotlight@mail.[third-party]professional.com. The subject heading for each of the emails read:

- Explore data from the JAVELIN Bladder 100 trial
- Guideline recommendations in locally advanced or metastatic urothelial carcinoma (UC)
- Explore efficacy data of a first-line maintenance treatment option in locally advanced or metastatic urothelial carcinoma (UC)
- Manageable tolerability of a first-line maintenance treatment option in locally advanced or metastatic urothelial carcinoma (UC)

The subject lines of each of the four types of emails were also included as a large heading in the body of the email beneath which in small pale grey text was 'Information from Industry'. The emails then featured brief text, normally in the form of a question to encourage the recipient to click the button below labelled "Learn more (external link)" which led the user to a Merck Serono promotional website for Bavencio.

The Panel noted that Merck Serono's response referred to a landing page and that it was apparent from a large statement on the landing page that the user would be entering the "Merck Immuno-Oncology Website". Below the heading in smaller text was a sentence to explain the site was intended for health professionals only and contained educational and promotional materials relating to Merck products. There were also two buttons for the user to select, one to confirm they were a UK health professional and the other if the user was not a health professional. The user would then be taken to webpages that were relevant to the email.

Upon selecting "Yes I am a HCP", the user would then be directed to a promotional webpage for Bavencio; the Panel did not have copies of the promotional webpages to which each version of the email directed users. Both parties agreed that the webpages in question were promotional.

The Panel noted that Merck Serono's response implied that this campaign was a one-off arrangement, however, it was apparent that the agreement between the third-party medical publisher and Merck Serono was part of an ongoing commercial contract.

The Panel noted that the content of the invitation emails was different. According to the versions provided by the complainant the subject title read 'We've hand-picked exclusive invitations just for you'. Upon opening, the initial text on the versions provided by the complainant was not complete and read '….are waiting for you'. The invitation emails then listed four separate invitations from different companies, each within an outlined box, which invited the reader to use a link to access material about different cancers. Each invitation email included one Merck Serono invitation. The invitations within each email did not appear to be related to each other. The Merck Serono invitations appeared to be identical in each email provided and were headed 'Javelin Bladder 100 trial. Can mOS be improved in locally advanced or metastatic urothelial carcinoma?' above an external link. Beneath, in small black font, 'Promotional advertisement from Merck for UK health professionals' sat above an adverse event reporting statement. An apparent link to Bavencio prescribing information sat beneath followed by a tab which read 'ENTER' and appeared to be a link to external material. According to the complainant the invitation emails were similarly sent from the third-party medical publisher's email address.

The Panel noted that Merck Serono did not provide a substantive response in relation to the invitation emails but considered that given Merck Serono had been provided with copies when notified of the complaint, its response was applicable to the invitation emails and the Panel would rule upon them accordingly.

According to Merck Serono, the campaign ran from 30 August 2023 to 18 December 2023. It was unclear whether this included the invitation emails.

Disguised Promotion

The complainant alleged that the main emails and invitation emails in question were sent from a third-party medical publisher email address suggesting that the content was non-promotional, and the subject line of the emails did not suggest any promotional intent either.

Clause 15.6 stated that promotional material must not be disguised. Its supplementary information provided that the identity of the responsible pharmaceutical company must be obvious.

Clause 5.5 of the Code requires that material in which a pharmaceutical company has any involvement must clearly indicate the role of that pharmaceutical company. The supplementary information to Clause 5.5 includes that the wording of the declaration of involvement must be unambiguous so that readers are immediately able to understand the extent of the company's involvement and influence. This is particularly important when companies are involved in the production of material which is circulated by an otherwise wholly independent party. The declaration of sponsorship must be sufficiently prominent to ensure that readers of sponsored material are aware of it at the outset.

The Panel firstly considered the main four types of email and disguised promotion. The Panel noted its description of the emails above, and that neither the sender email address nor the subject line referred to Merck Serono or indicated that they were otherwise promotional. The Panel also considered that the impression given by the four main types of email was that they linked to a non-promotional website to provide an update on clinical data and that was not the case. The Panel did note that the content of the emails contained the same statement, within the body of the email (around two-thirds of the way down the page): 'promotional advertisement from Merck for UK healthcare professionals'. However, the text was so small, and the location was such that readers would not be aware of the company's involvement at the outset and certainly not before they had opened and read the email.

Additionally, at the footer of the emails, outside of the outlined promotional content, the text, 'the information contained in this email is brought to you by a third-party sponsor. This promotional communication is provided by [named medical publisher Professional Spotlight Third-party medical publisher LLC., who does not endorse or is responsible for the accuracy of the content' was included. The Panel considered that neither the content of the text nor its location was sufficient to mean that the promotional nature of the email was clear at the outset.

Given the comments and observations above, the Panel considered that the combined effect of the sender's email address and email subject line were such that the promotional nature of the email and linked material were not clear at the outset and were thus disguised. This misleading impression was compounded by the failure to make the role of the company prominent and clear at the outset within the email. The Panel ruled **breaches of Clause 15.6** of the Code in relation to each of the four main email types.

In relation to the invitation emails and disguised promotion the Panel noted that these were slightly different as the banner design of the Merck Serono invitation meant that the statement 'Promotional advertisement from Merck for UK health professionals' sat immediately beneath and thus within the immediate visual field of the prominent invitation heading 'Javelin Bladder 100 trial. Can mOS be improved in locally advanced or metastatic urothelial carcinoma?' Nonetheless the Panel noted that the Merk Serono invitation was not the first invitation listed within the invitation emails provided by the complainant and thus it would not always be immediately apparent that the invitation emails contained promotional invitations. Irrespective of

where the Merck Serono invitation appeared within the invitation emails the Panel noted the email subject heading and sender's email address and considered that its comments above in this regard in relation to the four main emails applied here. The Panel considered that the combined effect of the sender's email address and email subject line were such that the promotional nature of the discrete Merck Serono invitation which sat within the invitation emails was not clear at the outset and was thus disguised. **A breach of Clause 15.6** was ruled in relation to the Merck Serono invitation, which was identical within each invitation email provided by the complainant.

The Panel noted that the complainant's concern appeared to be that the initial impression given by the sender's email address and email subject line was such that the four main emails and the invitation emails were disguised promotional material. On balance, in the Panel's view, the complainant had not made a distinct allegation that Merck Serono's involvement was not clear, rather it was the nature of Merck Serono's material, promotional or non promotional, that was not clear at the outset. The Panel accepted that there was a degree of overlap between Clause 15.6 and Clause 5.5 but considered that in the particular circumstances of this case, the complainant had not made a clear separate allegation on this point, they appeared to be clear that Merck Serono was involved in the material. The Panel therefore decided that it did not have a valid allegation under **Clause 5.5 and ruled no breach** accordingly in relation to each of the four types of main email and the invitation email.

Consent to receive emails and the ability to unsubscribe

In the Panel's view there was no allegation relating to the user being able to unsubscribe from receiving the emails, or whether the complainant had given adequate consent to receive the emails, rather the complainant wanted to receive less frequent email traffic regarding this campaign.

The Panel noted Merck Serono's detailed submissions on consent to receive emails.

Noting the Panel's view, that there was no allegation about consent, and whether the email was tailored towards the recipient, the Panel ruled **no breach of Clauses 5.6 and 15.5**. This ruling applied to each of the four main emails and the invitation emails.

Similarly, the Panel did not consider that there was an allegation about the ability to unsubscribe from the email. The complainant, in the Panel's view, wanted to receive the emails less frequently and asked a rhetorical question about unsubscribing from 'getting these every 4 days whilst not losing out on breaking news which would be worth reading,' which was different to asking not to receive the emails at all. Merck Serono had responded in relation to the requirements of Clause 5.1 and what it interpreted as an alleged failure to permit the complainant to unsubscribe altogether. Given it considered that there was no allegation on this point the Panel ruled **no breach of Clause 5.1** on this narrow point. This applied to each of the four main emails and the invitation emails.

Frequency of emails

Clause 16.3 stated that restraint must be exercised on the frequency of distribution and on the volume of promotional material distributed. The supplementary information added that criticism of their [the material's] frequency was most likely to arise when the information content was limited.

The Panel noted that the complainant received four different types of emails with differing topics and invitation emails all ultimately related to the promotion of Bavencio. The emails were received by the complainant at least every four days, and they provided evidence of their receipt on fourteen occasions.

The Panel noted Merck Serono's submission that the number of emails received by the complainant in the sixteen-day period was in line with the third-party medical publisher's standard practice which was determined as an acceptable level of communication. The Panel noted Merck Serono's submission that dependent on the number of target click-throughs, the medical publisher adjusted the frequency of emails up to a maximum frequency of one email every sixteen days for each of the four types of emails, which was a threshold that the medical publisher determined was the limit of acceptable frequency. This meant that in each sixteen-day period a recipient received each of the four types of emails, which Merck Serono submitted was in line with the frequency that the complainant received. This was the third-party medical publisher's standard practice and Merck was neither involved nor had any visibility of this decision. To further monitor whether the frequency was acceptable to the recipients, the medical publisher tracked unsubscribe rates, which for the campaign were low at 0.03%, suggesting that most recipients were comfortable with the frequency of e-mail communication.

The Panel noted that according to Merck Serono's frequency table it appeared that in October, an email was sent every 3.9 days and in November every 4.3 days. The Panel also noted from the same table, that several emails with the same job number were duplicated in October, November and December. The matter was further complicated by the fact that the invitation email bore the same job bag number as one of the four main types of email, UI-AVE-00125, despite having different layout and content. Both referred to the JAVELIN Bladder 100 trial. It was wholly unclear whether the frequency table included the invitation email. The complainant had provided copies of invitation emails dated 8 November, 22 November and 27 November 2023.

The Panel considered that it was a well-established principle that pharmaceutical companies were responsible for work undertaken by third parties on their behalf. In the Panel's view Merck Serono ought to have satisfied itself that restraint on the frequency of emails satisfied the requirements of Clause 16.3 of the Code. It could not delegate responsibility in this regard.

The Panel noted that the frequency of the emails was such that the complainant had been minded to contact the PMCPA with a complaint. The Panel bore in mind its ruling of a breach of the Code with regard to disguised promotion. The Panel, noting its comments and ruling above, considered that the frequency of the emails sent to one recipient in a short time frame which the Panel had decided was a disguised promotional activity was such that restraint on the frequency of emails had not been exercised and amounted to a **breach of Clause 16.3** of the Code. This ruling applied to the overall frequency of distribution of the four main types of emails and the invitation email irrespective of whether the latter was included in the frequency table.

<u>High Standards</u>

The Panel were concerned about Merck Serono's apparent lack of due diligence and lack of awareness that it was accountable for the medical publisher's actions in delivering the promotional campaign; in particular it did not appear that Merck Serono had ensured that that

restraint on the frequency of distribution of its emails had been applied and complied with the Code. The Panel therefore considered that Merck Serono had failed to maintain high standards and ruled a **breach of Clause 5.1** of the Code.

Complaint received **18 December 2023**

Case completed **4 April 2025**