CASE AUTH/3894/4/24 *NO BREACH OF THE CODE*

COMPLAINANT v MERCK SERONO

Allegations about a health professional's LinkedIn post

CASE SUMMARY

This case was in relation to a LinkedIn post made by a UK health professional who had been contracted by Merck Serono's parent company based in Germany, to speak at a meeting in Barcelona, Spain. The post included a link to the slides presented at the meeting. The complainant alleged, among other things, that the post constituted promotion to the UK public.

There was an appeal by Merck Serono of five of the Panel's rulings. The Appeal Board determined that the case was out of scope, therefore no breaches of the 2021 Code were ruled:

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 3.6	**Requirement that materials and activities must not be disguised promotion**
No Breach of Clause 5.1 (x3) [Panel's breach ruling overturned x2]	**Requirement to maintain high standards at all times**
No Breach of Clause 8.3	**Requirement to certify non-promotional material**
No Breach of Clause 12.1 [Panel's breach ruling overturned]	**Requirement to include up-to-date prescribing information**
No Breach of Clause 26.1 [Panel's breach ruling overturned]	**Requirement to not advertise prescription only medicines to the public**
No Breach of Clause 26.2 [Panel's breach ruling overturned]	**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 or encourage the public to ask their health professional to prescribe a specific prescription only medicine.**
No Breach of Clause 26.4	**Requirement to include a 'reporting of side effects' statement in any material which relates to a medicine and which is intended for patients taking that 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 about Merck Serono Limited was received from an anonymous, non-contactable complainant.

COMPLAINT

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

> "GL-Mav-01106 Promotion to the UK public on LinkedIn by a UK HCP. Breach of Clause 26.2 and 26.2. No prescribing information therefore breach of Clause 12.2 Disguised promotion Breach of Clause 12.1 No adverse event reporting breach of 26.4. Not certified breach of Clause 8.3. Breach of high standards Clause 9.1. Companies are responsible under the Code for the acts and omissions of their third parties which come within the scope of the Code, even if they act contrary to the instructions which they have been given. Breach of Clause 2."

When writing to Merck Serono, the case preparation manager (CPM) noted that the complainant appeared to have cited a mixture of clauses from the 2019 and 2021 Codes, however, as the activity took place in April 2024, the CPM asked Merck Serono to consider the requirements of the closely similar clauses, Clauses 2, 3.6, 5.1, 8.3, 12.1, 26.1, 26.2 and 26.4 of the 2021 Code.

MERCK SERONO'S RESPONSE

The response from Merck Serono is reproduced below with some typographical errors corrected:

> "Thank you for your letter dated 1 May 2024, concerning alleged breaches of the ABPI's Code of Practice for the Pharmaceutical Industry (the '**Code**'). I can reassure you that Merck Serono UK Limited ('**Merck**') seeks to both fully comply with and embody the Code in all our activities.
> The complainant alleges numerous purported breaches of the Code, and you have asked us to consider Clauses 2, 3.6, 5.1, 8.3, 12.1, 26.1, 26.2 and 26.4 of the Code, as well as considering the requirements of Clauses 1.2 and 8.2 and the accompanying supplementary information. Further, you requested an original or good quality colour copy of the material at issue, together with details of how the material was used, a copy of the certificate approving the material in question and qualifications of the signatories, a copy of the relevant Summary of Product Characteristics (SmPC), together with copies of the contract with the consultant and the briefing provided for the same. The certificate is not included for reasons as outlined below – all other requested materials can be found in the attachments.
>
> The complaint revolves around a social media posting of Merck materials (the '**Complaint**'). However, what is peculiar about the Complaint is that the actions leading to the purported breaches are not as a result of any action or inaction by Merck, but by a post made by a healthcare professional (HCP) on the social media platform LinkedIn. Central to the Complaint is the fact that a healthcare professional has breached the Code after a UK-based HCP posted slides that they had presented at a medical education meeting in Barcelona, Spain on 27 April 2024 (the '**Event**'). The Event was organised and sponsored by Merck KGaA, Darmstadt, Germany, (hereinafter '**Merck**

Global'), which is the parent company of Merck and the global headquarters of the healthcare division of the Merck Group of companies; for clarity, subsequent references to Merck relate to Merck Serono, whereas Merck Global refers to Merck KGaA. The Event was intended for a global audience of HCPs involved in the diagnosis and management of patients with multiple sclerosis (MS).

The UK-based HCP was contracted by Merck Global to provide services to both prepare and present a talk, as well as participate in a panel discussion at the Event. Details of the contract are provided.

The Event was educational (as opposed promotional), was designed for a global audience of relevant HCPs, and organised by Merck Global, with no involvement of Merck. As the Event took place in Barcelona, Spain, the meeting and materials prepared by the UK HCP were reviewed by Merck Global, in accordance with local regulations in Spain, as the host country. It is our contention, therefore, that the Code is neither relevant nor applicable to the slides prepared by the UK -based HCP. Notwithstanding, only after the meeting had finished, the UK-based HCP shared the slides that [they were] contracted to prepare for the session via [their] private LinkedIn account.

In investigating the Complaint, Merck has sought clarity from the HCP in question, and [they have] provided confirmation that (i) it is normal practice to [them] to share educational presentations [they have] given – the HCP is a global leader in educating other HCPs in diagnosing and treating MS and in managing patients to allow them to maximise their quality of life after being diagnosed with MS; and (ii) at no point [were they] asked, invited, or instructed to share any content of [their] educational presentation on any social media channel(s) by any employee(s) of Merck, Merck Global or any other subcontractor(s) of Merck or Merck Global.

Given that the HCP acted of [their] own volition, Merck Global only became aware once the LinkedIn post was up and shared; several people in the Merck Global medical affairs team subsequently became aware of the post and the HCP was asked to remove it as some of the content may not be suitable for a broad LinkedIn audience that could include non-HCPs. The HCP agreed to remove the post. Please note that at no point were Merck staff aware or informed of the post or its removal; we first became aware of this matter following your letter of 1 May 2024.

Specifically addressing the alleged breaches of the Code:

- Merck is an affiliate of Merck KGaA, Darmstadt, Germany; as Merck was not involved in either the contracting or briefing of the speaker, Clause 1.2 cannot apply.

- The Event slides were not in scope of the Code, because the Event was an educational event organised and funded by Merck Global for a global audience held outside of the UK. Accordingly, there cannot be any breaches of Clauses 3.6, 5.1, 8.3, 12.1, 26.1, 26.2, 26.4.

- The only involvement of the UK-based HCP was to act as a speaker at the educational event and was under contract by Merck Global; therefore Clause 8.2 cannot apply.

- Merck was neither involved in the Event nor in briefing the UK-based HCP for the same; therefore Merck cannot be in breach of Clause 2 of the Code.

Summary & Conclusion

In summary, Merck's stance is simply that the Code is not relevant to the subject of any of the materials or activities involved in the Event, and therefore all the allegations made in the Complaint should be dismissed."

PANEL RULING

This case was in relation to a LinkedIn post made by a UK health professional who had been contracted by Merck Serono's parent company based in Germany, to speak at a meeting in Barcelona, Spain. The LinkedIn post included a link to a set of slides presented at the meeting and stated:

> "acadeMe_MS Barcelona – Apologies, my slides for today's presentation are too data-heavy to get through all the information in 37 minutes. You can download the PDF using the link below to follow my presentation => [link]."

The LinkedIn post also contained an image of the opening slide of the linked presentation which featured a large image of a brain, with the following adjacent text:

> "TREATMENT STRATEGIES IN MS:
> An updated clinical perspective
> Barcelona, 27th April 2024."

This was followed by a prominent title for the presentation in bold font: "Expanding our understanding of IRTs [immune reconstitution therapies] in MS [name of presenting health professional]" beneath which appeared the following text in much smaller font:

> "GL-MAV-01266 / UI-MAV-01106 I April 2024
> This medical programme is funded and organised by Merck Healthcare KGaA, an affiliate of Merck KGaA, Darmstadt Germany. EMD Serono is the healthcare business of Merck Healthcare KGaA, Darmstadt, Germany, in Canada. It is intended for healthcare professionals only, (excluding US healthcare professionals). The materials shown are intended for discussion purposes and must not be considered medical advice from healthcare professionals. Scientific opinions presented therein do not necessarily represent the position of Merck. It is not intended to promote the use of any products. Prescribing information may vary depending on local approval in each country. Therefore, before prescribing any product, always refer to locally approved prescribing information and/or the Summary of Product Characteristics (SmPC). The presentations may contain information on products and/or product combinations outside of the approved label in the EU and/or in your country. For any further information regarding the approval status of a specific product in your country, please refer the applicable product labelling information in your country of practice.

The Panel noted that the opening slide included a prominent Merck logo on the bottom right in bright pink font.

Merck submitted that the educational meeting was organised by its overseas parent affiliate, "Merck Global", and was intended for a global audience of health professionals involved in the diagnosis and management of patients with multiple sclerosis. The UK-based health professional who gave the presentation, and made the LinkedIn post at issue, was contracted by Merck Global to provide services to both prepare and present a talk, as well as participate in a panel discussion at the meeting.

The Panel noted Merck's assertion that the slides were not in scope of the Code, because the event was an educational meeting organised and funded by Merck Global for a global audience held outside of the UK. Merck submitted that, as the UK affiliate was not involved in either the contracting or briefing of the speaker, Clause 1.2 could not apply.

The Panel noted that it was an established principle that pharmaceutical companies were responsible for the acts and omissions of their third parties which came within the scope of the Code, even if such acts and omissions were contrary to the instructions which they had been given. Furthermore, UK companies were responsible for the acts and omissions of their overseas affiliates that came within the scope of the Code. It therefore followed that a company would be responsible for any acts or omissions of its global parent company and/or its third parties that came within the scope of the Code.

The Panel observed that the content of the service agreement between the health professional and Merck Global included a section titled "Representations, Warranties and Obligations" which stated, among other things, that:

> "The Parties agree to comply with all applicable international, regional, national, and local laws, directives, regulations, ordinances, competent authorities' decisions and guidelines ("Applicable Laws")",
>
> "The Parties further agree to comply with the applicable requirements of the Association of the British Pharmaceutical Industry Code of Practice ("ABPI Code")", and
>
> "In-person presentations related to the Services shall occur in locations appropriate to providing the Services and, to the extent relevant, in accordance with the geographic location requirements of the ABPI Code."

Firstly, the Panel had to decide whether the UK-based health professional's LinkedIn post, and linked presentation slides, were within the scope of the Code. The Panel considered that companies should assume that the Code would apply to, and that companies would be responsible for, all personal social media activity that fell within the scope of the Code by their employees and individuals working for the company, unless, for very clear reasons, it could be shown otherwise. Any material associated with a social media post, for example a link within a post, would normally be regarded as being part of that post.

The Panel observed that the LinkedIn post at issue included a link to a presentation with 57 slides. One slide, titled "Treatment persistence and adherence following initiation of treatment

with cladribine tablets, Real-world evidence" included three infographics illustrating treatment persistence and adherence data for cladribine tablets in UK and US populations. The two infographics representing UK data appeared beneath a bold subheading, "UK population" within a purple banner which included a picture of the Union Jack flag, the number of patients (N=2,684), and referred to a 5-year follow-up. The first infographic stated that "89% [of patients] either completed treatment or were assumed to remain on treatment at time of analysis" and the second infographic stated "93% did not switch to another DMT".

Clause 1.2 stated "Information or promotional material about medicines which is placed on the internet outside the UK will be regarded as coming within the scope of the Code, if it was placed there by:

- a UK company/with a UK company's authority, or
- an affiliate of a UK company, or with the authority of such a company, and it makes specific reference to the availability or use of the medicine in the UK."

The Panel noted that the LinkedIn post originated from a UK-based health professional and that the beginning of the LinkedIn post stated their role as a professor at a UK university. The Panel also considered that the presentation made specific reference to the availability or use of cladribine in the UK.

The Panel noted that the health professional, who presented the slides at the meeting, and provided services to Merck Global, resided in the UK. The Panel considered, on the balance of probabilities, that a reasonable proportion of the individual's connections on LinkedIn would therefore be UK residents and the LinkedIn post at issue was, on the balance of probabilities, directed towards a UK audience.

The Panel concluded that the proactive dissemination of information that referred to the use of cladribine in the UK, to a UK audience, from the LinkedIn account of a UK-based health professional acting on behalf of Merck Global, brought the post, and the presentation to which it linked, within the scope of the UK Code.

The next matter for the Panel to decide was whether the linked presentation was promotional. The Panel noted that the presentation, which was titled "Expanding our understanding of IRTs in MS" included an introduction section which briefly discussed early and late interventions in MS treatment, the prevalence of MS by age group and pathological drivers of central inflammation and its markers. This was followed by a section titled "IRTs in the current MS era" which included detailed slides about cladribine tablets as an effective treatment for relapsing forms of multiple sclerosis, how they work, the dosing schedule, and their safety and efficacy profile. The final section of the presentation, titled "An unmet medical need in addressing CNS-compartmentalised inflammation remains" discussed the MAGNIFY-MS trial in which serum NfL levels were measured at 12 and 24 months following treatment with cladribine compared with baseline, and the CLARITY trial which measured grey matter atrophy over 2 years in patients with RRMS [relapsing-remitting multiple sclerosis] treated with cladribine tablets. Both trials illustrated positive outcomes for patients treated with cladribine.

The Panel observed cladribine was mentioned 134 times in the presentation slides and determined that these slides, which primarily discussed the use of cladribine tablets and trial data, could not be seen as anything other than promotional. The Panel considered the LinkedIn

post and the presentation slides in totality, and made its rulings on the basis that these were promotional.

The Panel considered that, on the balance of probabilities, not all of the UK-based health professional's connections on LinkedIn would meet the Code's definition of a health professional or other relevant decision maker and therefore the information had likely also been made available to members of the public.

The Panel concluded that cladribine had been promoted to members of the public and ruled a **breach of Clause 26.1** accordingly.

The Panel also considered that the presentation, which included extensive information on the use of cladribine and positive outcomes of treatment, might encourage readers to ask their health professional about treatment with cladribine. The Panel therefore ruled a **breach of Clause 26.2**.

The Panel noted the allegation regarding the failure to certify, but that the complainant had cited a breach of Clause 8.3 which required that certain non-promotional materials must be certified in advance in a manner similar to that provided for by Clause 8.1, which covered the certification of promotional material. The Panel noted its determination above that the LinkedIn post was promotional and therefore considered that Clause 8.3 was not relevant and **no breach of Clause 8.3** was ruled. The Panel, however, noted that the LinkedIn post had not been certified and considered that failure to certify this promotional post in line with Clause 8.1 meant that high standards had not been maintained and a **breach of Clause 5.1** was ruled in this regard.

Regarding the allegation about the omission of prescribing information, the Panel noted the opening slide, which was displayed in the LinkedIn post, stated "Prescribing information may vary depending on local approval in each country. Therefore, before prescribing any product, always refer to locally approved prescribing information and/or the Summary of Product Characteristics (SmPC)". Not only was this wording included in very small font which, in the Panel's view, would be illegible if viewed on a mobile device, it also only referred in general terms to a need to refer to the "locally approved prescribing information".

In any event, Clause 12.1 requires that the prescribing information listed in Clause 12.2 must be provided in a clear and legible manner in all promotional material for a medicine. The Panel, noting that neither the LinkedIn post, nor the linked presentation slides, included the UK prescribing information, considered the requirements of Clause 12.1 had not been met. A **breach of Clause 12.1** was ruled.

In relation to the allegation that there was no adverse event reporting statement, the complainant appeared to have incorrectly cited Clause 26.4 which applied to any material which relates to a medicine and which is intended for patients taking that medicine. The Panel noted its determination that the LinkedIn post at issue, and the linked presentation slides, were promotional material and therefore not intended for patients taking cladribine. On that narrow technical point, the Panel ruled **no breach of Clause 26.4**. Nonetheless, the Panel considered the omission of a prominent adverse event reporting statement as required in Clause 12.9 for all promotional material, meant that high standards had not been maintained. A **breach of Clause 5.1** was ruled in this regard.

In relation to the disguised promotion allegation, the Panel considered that the Code did not require promotional material to be labelled as such; however, promotion must not be disguised.

Although the complainant alleged disguised promotion, they had not provided further details to explain their rationale for why this amounted to disguised promotion. It was not for the Panel to make out a complainant's allegations.

The Panel considered the immediate and overall impression created by the LinkedIn post which included an image of the opening slide featuring the prominent headings "TREATMENT STRATEGIES IN MS" and "Expanding our understanding of IRTs in MS", along with a prominent Merck logo in the bottom right corner in bright pink font. In the Panel's view, readers would reasonably expect the linked presentation to include information about Merck's product(s) in multiple sclerosis.

The Panel considered that the complainant bore the burden of proof. The complainant had not established that the promotional nature of the LinkedIn post or the presentation slides was, on balance, disguised. **No breach of Clause 3.6** was ruled.

The Panel considered that Merck UK had been let down by a UK-based health professional, acting on behalf of its overseas parent company, resulting in the dissemination of information about its medicine. The Panel noted Merck's submission that the UK affiliate was not aware of the LinkedIn post at issue, or involved in the organisation or funding of the meeting, nor engagement of the UK-based health professional. The Panel considered that the complainant bore the burden of proof and did not consider that they had established that Merck UK had failed to maintain high standards, other than in relation to the breaches already ruled above, and **no breach of Clause 5.1** was ruled. For the same reasons, the Panel also ruled **no breach of Clause 2**.

APPEAL BY MERCK SERONO

Merck Serono's written basis for appealing is reproduced below with some typographical errors corrected:

> "We are in receipt of your letter dated 12 May 2025, setting out the Panel's Decision regarding allegations of, amongst others, promotion to the public, disguised promotion, material not certified and failure to maintain high standards (the "Complaint"). The Panel considered the allegations and found Merck to be in breach of Clauses 26.1, 26.2, 5.1 (twice) and 12.1. No breaches of the Code regarding Clauses 8.3, 26.4, 3.6, 5.1 and 2 were found.
>
> Merck respectfully submit that the Panel has erred in its Decision on the most fundamental basis – the applicability of the Code in the first instance:
>
> > "Clause 1.2 stated 'Information or promotional material about medicines which is placed in [sic] the internet outside the UK will be regarded as coming within the scope of the Code, if it was placed there by:
> >
> > - A UK company / with a UK company's authority; [Limb 1] **or**

- An affiliate of a UK company, **or** with the authority of such a company, **and** it makes specific reference to the availability or use of the medicine in the UK" [Limb 2]

  [emphasis added]

All the breaches of the Code the Panel found flow from the above understanding, which Merck submits is flawed. Indeed, the Panel go further at the end of the letter, stating

> "[t]he Panel considered that Merck UK had been let down by a UK-based health professional, acting on behalf of its overseas parent company, resulting in the dissemination of information about its medicine. The Panel noted Merck's submission that the UK affiliate was not aware of the LinkedIn post at issue, or involved in the organisation or funding of the meeting, nor engagement of the UK-based health professional. The Panel considered that the complainant bore the burden of proof and did not consider that they had established that Merck UK had failed to maintain high standards, other than in relation to the breaches already ruled above, and **no breach of Clause 5.1** was ruled. For the same reasons, the Panel also ruled **no breach of Clause 2**."

Dealing with the Panel's own Decision, it is clear that Merck UK is not at fault, as set out above. Accordingly, Limb 1 of Clause 1.2 cannot be satisfied.

With regard to Limb 2, there are two elements: the first deals with an affiliate of a UK company or with the authority of the same; the second part "[and]" indicates reference to the UK market. However, it therefore follows that there can be no offence if the first part of Limb 2 cannot be satisfied. In other words, the Panel has not adduced, nor did the complainant provide, any evidence indicating that either Merck Global had placed the information on the internet, or that the HCP in question had done so with the authority of the same. The evidential burden has not been satisfied, and as Merck submit, the first part of Limb 2 cannot be satisfied, and as a result all the alleged breaches identified cannot materialise as the Code is not in scope.

To supplement our position, we draw your attention to Clause 8.3 of the Service Agreement, which unequivocally states that "[a]ll work developed under this Agreement, including but not limited to data, notes, plans, documentation, and reports ("Work Product"), shall be the sole property of Company." The Slides presented at the meeting in Barcelona were and indeed remain the property of Merck. However, this does not in and of itself bring Merck (either Global or UK) under the auspices of and/or in breach of the Code; the important point is usage of such slides.

The HCP was contracted to speak at the meeting in Barcelona on 27 April 2024. Following the closure of the meeting, the HCP ceased to be a provider to Merck because the Service Agreement has been terminated – the services have been provided and complete and at such a point the HCP can no longer be deemed to be acting on behalf of Merck Global. As such, at the time the HCP shared the slides on LinkedIn, [they were]

no longer under contract. Accordingly, Merck submit we cannot be held liable for the acts or omissions of service providers no longer under contract. If, as the Panel contend, Merck Global are accountable, which brings the Code into scope – a point Merck refute for lack of evidence – a more general question would be at what point does a service provider cease to be one? The Panel's view appears to be indefinite, in this case notwithstanding any evidence that the HCP was acting under the authority of Merck Global.

As a final point, the [senior medical leader] for Merck Global, upon being alerted to the LinkedIn post in the first instance, made contact with the HCP, who subsequently removed the post. On any interpretation of the situation, it seems hard to conclude that such an action could be deemed express and/or implied authority of Merck Global; quite the contrary.

By the Panel's own admission, Merck UK was let down by the actions of the HCP acting independently and indeed on a frolic of [their] own. We submit this same scenario applies to Merck Global. Therefore, the Code cannot be in scope and there cannot be any subsequent breach of the Code.

We thank you in advance for your consideration.''

APPEAL BOARD RULING

The Appeal Board observed that Merck Global (Merck Serono's parent company based in Germany) had engaged a UK health professional to give a presentation at a meeting it had organised and funded that took place in Spain. The meeting was intended for a global audience of health professionals. Merck UK submitted that it:

1. had not invited any UK delegates to the meeting,
2. considered the speaker's LinkedIn post, which included a link to their presentation slides, to be a breach of their speaker's contract, and
3. contacted the speaker (once it had been alerted to the LinkedIn post by Merck Global), and the speaker had subsequently removed the post.

The Appeal Board considered the requirements of Clause 1.2, which stated:

"Information or promotional material about medicines which is placed on the internet outside the UK will be regarded as coming within the scope of the Code, if it was placed there by:

- a UK company/with a UK company's authority, or
- an affiliate of a UK company, or with the authority of such a company, and it makes specific reference to the availability or use of the medicine in the UK."

On the particular facts of this case, the Appeal Board accepted Merck's submission that Merck UK:

1. did not organise or fund the meeting, nor engage the UK-based health professional as a speaker,

2. was not responsible for placing the presentation slides on LinkedIn and nor was that done with its authority, and
3. was unaware of the LinkedIn post until alerted to it by Merck Global.

The Appeal Board further considered that in addition to the presentation slides not having been placed on LinkedIn with the authority of Merck UK, they were not placed there with the authority of Merck Global either.

For these reasons in combination, the Appeal Board concluded that Clause 1.2 had not been engaged and thus the LinkedIn post, including the linked presentation slides, was not in scope of the Code. The Appeal Board ruled **no breaches of Clauses 5.1(x2), 12.1, 26.1 and 26.2** as the matter was not within the scope of the Code. The appeal was successful.

Complaint received **27 April 2024**

Case completed **19 June 2025**