CASE AUTH/3794/7/23

COMPLAINANT v MERCK SERONO

Allegations regarding a Merck Serono meeting

CASE SUMMARY

This case was in relation to a Merck Serono fertility event. The complainant alleged, among other things, that two health professional speakers had not signed their contracts.

The outcome under the 2021 Code was:

Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 24.2 (x2)	**Failing to agree a written contract or agreement in advance of the commencement of services**

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**

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 was received from an anonymous, non-contactable complainant, who described themselves as a fertility specialist.

COMPLAINT

The complaint wording is reproduced below:

> "I am writing to you reluctantly to inform you of an unfortunate Pharma sponsored educational meeting last week-16th June – which I attended in my capacity as a Fertility specialist. The meeting was organised by Merck Fertility – or as one of their employees referred to it as 'Serono'.
>
> This meeting was held in [a hotel in London] and was attended by a large crowd of approximately 60 of our Fertility fraternity.
>
> It was extremely evident that the meeting was causing a great amount of stress to the company employees present – moreover due to the fact that we heard their [senior legal and compliance employees] were both in the room. This may have been because

both the main speakers had refused to sign their speaker SLA's/contracts prior to the meeting – although the meeting did go ahead.

Moreover the 'Serono' speaker encouraged the audience to stand in for a photo which [they were] anxious to post on social media. Needless to say – no one allowed this to happen.

I feel that this company event brought reputational damage to the industry – as it tries to be seen as a partner to Clinicians."

When writing to Merck Serono, the PMCPA asked it to consider the requirements of Clauses 2, 5.1 and 24.2 of the Code.

MERCK SERONO'S RESPONSE

The response from Merck Serono is reproduced below:

"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 one of our recent promotional events (the "**Event**", and collectively the "**Complaint**").

The "*Concerned Fertility Specialist*" (the "**Complainant**") alleges a number of issues, namely (i) incorrect referencing of/to Merck; (ii) the speakers' contracts were not signed prior to the Event; (iii) photographic evidence of the Event may have been posted on social media; and (iv) potential reputational damage to the industry by Merck seeking to be seen as a partner to Clinicians. As you requested in your letter of 10 July 2023, we will address each of these under the relevant and applicable clauses of the Code: clauses 24.2 (Consultancy Arrangements), 5.1 (High standards) and 2 (Upholding Confidence in the Industry).

Background

Merck has been well-established in the fertility therapy area for many years. Accordingly, Merck has sought to engage healthcare professionals (HCPs) in fertility by organising the Event – the London Fertility Chapter – with two leading UK fertility HCPs. The Event was split into three distinct sections: two sections involved presentations from HCPs regarding clinical practice, and the third section featured a debate regarding US vs European IVF practice (no slides were shown for the debate). To assist you with context, we also attach the SmPC for the two products relevant to the Event; both Gonal-f and Pergoveris.

Clause 24.1

Clause 24.1 of the Code requires consultancy arrangements to be fulfilled, including but not limited to written contracts, agreed before the services begin, which specifies the exact services to be provided and the basis for payment of those services; and which requires the payment for those services to be reasonable and reflect the services' Fair Market Value ("**FMV**").

Addressing the Complainant's second allegation, regarding the HCPs presenting at the Event, two of the HCPs – [HCP 1] and [HCP 2] – signed contracts prior to the meeting and we attach those. However, the Complainant is indeed correct in alleging that the remaining two HCPs attending the Event – [HCP 3] and [HCP 4] – did not sign their contracts prior to the Event. The contracts were originally sent out to the relevant HCPs on 13 June 2023; [HCP 3] confirmed receipt but stated that the FMV and hours worked were not reflective of their [HCP 3 and HCP 4's] contribution and we attach relevant supporting documentation. The hours worked were revised and re-sent on 14 June 2023. The contracts were sent out before the Event, despite Merck seeking to obtain signatures from the HCPs, this proved unsuccessful. Although the HCPs had readily pointed out the purported disparity previously, they did not object to the proposed revisions. However, only on the day of the Event, we were informed by the HCPs themselves that they remained unwilling to sign the contracts because they thought (i) the hourly rate was "not appropriate" [*sic*]; and (ii) they believed they had worked significantly more hours than those suggested in the contracts. The FMV hourly rate for these HCPs had not changed since their last engagement; Merck believed the hours provided were a fair reflection of their contributions.

Merck's policy on Approval of Merck Serono Meetings, Support for, and Sponsorship to Attend, Third Party Meetings (the "**Policy**") states in Appendix 2 – Service Provider Engagement that Where HCP(s) provide services at events, the following criteria must be put in place prior to any service being provided – A written contract is put in place between the company/relevant affiliate and HCP. Furthermore, Merck's Quick Reference Guidance ("**QRG**") states that the written agreement must be in place prior to the engagement starting. In this instance, whilst compliant with the Policy, for the reasons set out above, two of the four contracts were not signed before the Event. The contracts remain in dispute with the HCPs, although Merck has (i) requested they provide evidence of their hours worked and (ii) reassessed the HCPs regarding the FMV hourly rate, both for the Event and any potential future interactions.

Merck provided briefing to the HCPs prior to the Event which is attached for reference. However, it appears the reason Merck finds itself in this position regarding the Complaint is that the briefing document was too vague – not in content, but in expectation. The briefing should normally contain the expected hours (and the hourly rate) of the contracting HCPs, and guidance on content, so that by the time the draft contract is received – well ahead of any activity – there can be no surprises. The briefing will be explored further when addressing clause 5.1, below.

Regarding the contracts themselves, Merck's belief, apart from the two contracts which were not executed, was that agreement had been reached with the HCPs presenting at the Event. However, it appears that the HCPs' perspective differed from our own; despite our best efforts, these contracts were not formally executed. Accordingly, given the requirements of the Code, Merck accepts a breach of clause 24.2 insofar as this relates to the execution, or lack thereof, to the relevant two (of four) contracts.

Clause 5.1

Merck seeks to maintain high standards at all times in all our interactions and activities. The crux of the issue concerning the Complaint revolves around the contracting, and in particular, the briefing first provided to the HCPs. The Event presentations were

certified and compliant with the Code, and we attach the certifier's credentials. However, although a formal briefing was supplied to the HCPs, other verbal communications had also taken place so that Merck could provide the HCPs with appropriate content guidance for the presentations. The written briefing supplied focuses on the actual day of the Event, and whilst useful, did not contain everything that was communicated via verbal conversations as well. As such it was not in keeping with our normal expectation of what a briefing for an event such as this should be, and we acknowledge on this occasion it led to ineffective communication regarding the expectations of the HCPs, which led to this Complaint.

Merck believes that in this instance, we have also been let down by the HCPs we chose to contract with. They had ample time with which to object to their contracts, yet chose to not sign their contracts, even right before the Event. The refusal appears to relate to their belated belief they should have had a higher FMV hourly rate – even though that rate had been made clear from the outset and had not changed from prior engagements – and that they had worked more hours that stated in the draft contracts.

Merck's policy is to execute contracts before any event occurs, to avoid situations such as this. In contrast to this Event, all meetings in our other two franchises (Neurology & Immunology and Oncology) have provided briefing documents that were certified well beforehand. Additionally, those meetings also provided speaker/chair briefings (well ahead of the meeting) on the content of their presentation, duration, number of slides, themes to cover and requests to provide the same to Merck in good time ahead of the meeting. If our normal practices were followed, it is highly unlikely the contractual issues arising with this Complaint would have transpired.

While our Policy and QRG cover this, we hold ourselves to the highest standards and are actively putting in place a plan to mitigate future engagements and ensure best practice across our business. We provide evidence of relevant employee training records. Notwithstanding, we will take firm action to ensure our team understands and upholds our best practice and policy, and strengthen the checks we have internally. We have a new process for contracting with HCPs, which includes a lead time notification, that if any activity is sent for approval within thirty (30) days of the activity taking place, any approval requires the intervention of a business manager. We will also be rolling out specific and robust individual training so our employees fully understand what is expected from them.

On this occasion, Merck acknowledges that we have fallen short of our normal high standards. In this instance, the key issue is the failure to formally execute two of the four HCP contracts. Although such failure was brought about by the last minute refusal by the HCPs themselves, the reality is our briefings should have been more comprehensive; accordingly, we accept a breach of clause 5.1 of the Code.

Clause 2

Merck believes that, notwithstanding the absent contracts of the relevant HCPs, it has in fact maintained confidence in the industry. All other contractual documents were in place and all materials were certified prior to the Event.

The Complainant also appears to suggest that Merck trying to "partner with Clinicians" brings reputational damage. We believe this is an unwarranted and inappropriate allegation to make, particularly as the Meeting Booklet states "*[i]n partnership with Merck*"; and it remains unclear what the Complainant is seeking to elicit by making this allegation.

Accordingly, Merck strongly refutes there has been any undermining of the confidence in the industry as a result of the Complaint.

Miscellaneous matters

Several minor matters remain to be addressed:

- At this juncture, it is timely to address the first issue raised by the Complainant, which is perhaps more complicated than it first appears. Merck has been in dispute with another pharmaceutical company – MSD/Merck & Co, Inc. – over the use of the name 'Merck'. Since the 1950s, the two companies reached a settlement whereby our company may utilise the name *Merck* everywhere in the world other than the US and Canada, where the company is known as EMD Serono (MSD use the name Merck & Co in the US and Canada). Although the Complaint does not make reference to any one individual, we presume that the Complainant is referring to one of our Global colleagues, whom has spent much of [their] career in the employment of EMD Serono, hence the use of the name is not incorrect, although not in common usage in Europe.

- A second point of clarification is that the Event took place on 15 June, and not as the Complainant states, on 16 June, despite asserting they attended the Event.

- The third point to raise is the reference by the Complainant concerning the "Serono speaker" (the **"Speaker"**) encouraging the audience to stand for a photograph. The Complainant alleged the Speaker was "*anxious to post [the photograph] on social media*" yet does not clarify this assertion. In any event, it is unclear what the Complainant is claiming from this assertion. There was a photograph taken, but the Speaker has confirmed there was no use of any photograph from the Event on any social media, and the Speaker has also confirmed its deletion.

- A final point to clarify is that the Complainant states the presence of Legal and Compliance employees at the Event suggests some sort of level of stress to Merck. However, although it is not a frequent occurrence, it is also not unusual for individuals from these teams to attend events such as this. Given (i) the new format of the Event, in particular the debate section; and (ii) the awareness of the two contracts yet to be signed, support from an overall compliance perspective was suggested and welcomed by the Merck team. Accordingly, Merck does not believe this to be pertinent to the Complaint.

Summary and Conclusion

Merck would like to reassure you that we take compliance with the Code extremely seriously. In responding to the Complaint, we accept that our contracting could and perhaps should have avoided the dispute we currently find ourselves in with the relevant HCPs. This dispute has meant that we did not strictly comply with Code in this one instance, but we have sought to mitigate this from happening again.

We confirm that our policies and procedures are always upheld to a high standard, except for this occasion which fell below our expected standards. The genesis of this Complaint occurred because of the briefing document, ultimately leading to the contracts not being signed due to differing expectations. Nevertheless, we believe there should not be any finding of undermining confidence in the industry because of this Complaint, for the reasons set out above."

PANEL RULING

The complainant alleged that both the main speakers at a Merck Serono fertility event had not signed their contracts prior to the meeting. Merck Serono stated that the event took place on 15 June 2023 and that two health professional (HCP) co-chairs ([HCP 3] and [HCP 4]) for the event had not signed their contracts.

Merck Serono submitted that the co-chairs had been sent their contracts on 13 June. The Panel noted an email from [HCP 3] to Merck Serono that same day, which stated:

> "I had requested this contract proposal many weeks ago, so am disappointed to receive it 48 hours before the event itself. The proposed hourly rate does not reflect our previous discussions and the proposed time taken for preparation does not reflect the reality of our [co-chairs] contribution to this event. Could you please review this proposal after discussion with [named individual] who I think has a better grasp on the hours of email exchange, Teams meetings and face to face meetings that have been involved."

The Panel considered that [HCP 3]'s email was clear that the co-chairs had already performed work in relation to the event, prior to receipt of the contract. In that regard, the Panel noted that the contract for each co-chair included services to be performed prior to the event, including 'consultancy for materials and debate topics'.

Merck Serono submitted that it had revised the hours worked in the contracts and re-sent them on 14 June; Merck Serono was of the understanding that the co-chairs did not object to the proposed revisions. However, on the day of the event, both HCPs remained unwilling to sign the contracts, and again disputed the hourly rate and the number of hours worked. The contracts remained in dispute with the co-chairs at the time of Merck Serono responding to this complaint.

Clause 24.2 stated, among other things, that a written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services.

The Panel considered that the contracts should have been signed prior to the commencement of any work (services) covered by that contract, and not just prior to the event itself. Nonetheless, the Panel noted that the allegation was specifically about failure to sign the speaker contracts prior to the event. The Panel noted that the consultancy agreements had not been signed by either co-chair prior to the event as alleged and the Panel ruled **a breach of Clause 24.2** in relation to each consultancy agreement.

The Panel noted that there were four external speakers, including the two co-chairs referred to above. Merck Serono submitted that the other two HCPs ([HCP 2] and [HCP 1]) had signed their contracts prior to the event. The Panel noted that [HCP 2] signed their contract on 14 June, the day before the event, even though their contract referred to slide preparation and review. [HCP 1]'s contract also referred to slide preparation and review, yet it was only sent to them on 13 June; they had signed the contract, but their signature was undated. The Panel considered, on the balance of probabilities, that these two speakers had commenced work (services) prior to signing their contracts. However, there was no allegation in relation to these two speakers. The complainant had only made an allegation in relation to "both the main speakers" who had "refused to sign" their contracts, which the Panel understood to mean the co-chairs.

The Panel noted the company policy provided ('Approval of Merck Serono Meetings, Support for, and Sponsorship to Attend, Third Party Meetings') was approved on 17 July 2023 and as such was not the policy which was in force at the time of the event (15 June 2023). The associated Quick Reference Guide ('QRG') was undated. The dates on the certificates for the training of the relevant employees ranged between 2019 and 2023; one certificate was dated 22 July 2023, more than a month after the event in question.

The Panel wholly disagreed with Merck Serono's submission that the co-chairs "…had ample time with which to object to their contracts". The co-chairs received their contracts 48 hours before the event, by which time they had already performed services in preparation for the event. The Panel did not have a copy of the policy in force at the time of the event and could make no assessment in this regard. The Panel considered that Merck Serono's management of the speaker contracts for the event in question was inadequate as it failed to ensure that contracts were signed in advance of the commencement of the services. In the Panel's view, high standards had not been maintained and the Panel ruled **a breach of Clause 5.1** of the Code, as acknowledged by Merck Serono.

With regard to the complainant's assertion that the Merck Serono speaker had encouraged the audience to stand in for a photo which they were "anxious to post on social media" but "**no one allowed this to happen**" (emphasis added by the Panel), the Panel considered that the complainant had not made an allegation in this regard and therefore the Panel made no ruling.

The Panel noted the complainant's allegation that the event brought reputational damage to the industry as it "tries to be seen as a partner to clinicians". It was not clear to the Panel what the complainant's concerns were in this regard. It was not for the Panel to infer reasons on behalf of the complainant who bore the burden of proof. Clause 2 was a sign of particular censure and reserved for such use. The Panel considered that the matter in relation to speaker contracts was sufficiently covered by its rulings of breaches of the Code above. The Panel considered that the complainant had not established that any of the matters raised brought reputational damage on the industry as alleged and the Panel ruled **no breach of Clause 2.**

Complaint received	**6 July 2023**
Case completed	**1 August 2024**