

CASES AUTH/3644/5/22 and AUTH/3694/10/22

COMPLAINANT v CROMA PHARMA

Excessive hospitality in relation to a Letybo launch symposium

CASE SUMMARY

This case was in relation to a Croma Pharma Letybo (botulinum toxin type A) launch symposium held in Monaco.

The Panel ruled the following breaches of the 2021 Code because it considered that the impression created by the arrangements of the symposium was such that hospitality, including the venue, did not appear to be secondary to the main purpose of the event, and this was compounded by the poor impression created by the signage:

Breach of Clause 5.1	Failing to maintain high standards
Breach of Clause 10.1	Providing inappropriate hospitality

For the poor impression created by the arrangements, noting that hospitality provided, in particular at international meetings, attracted public scrutiny and noting that the relevant supplementary information included matters of excessive hospitality, Croma Pharma was, on balance, ruled in breach of the following Clause of the 2021 Code:

Breach of Clause 2	Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
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**This summary is not intended to be read in isolation.
For full details, please see the full case report below.**

FULL CASE REPORT

An anonymous, non-contactable complainant who described themselves as a member of the public complained about a Croma Pharma Letybo (botulinum toxin type A) launch symposium held in Monaco in April 2022 (Case AUTH/3644/5/2022). Subsequently the Medicines and Healthcare products Regulatory Agency (MHRA) referred an identical complaint that it had received from an anonymous complainant to the Authority for consideration (Case AUTH/3694/10/22).

COMPLAINT

CASE AUTH/3644/5/22

The complainant stated that the Letybo launch symposium was attended by approximately 80 invited physicians, including several from the UK. The event was hosted by a named UK physician.

The complainant stated that the event was held in the ballroom at a five-star luxury venue which was also a member of The Leading Hotels of The World.

According to signage at the hotel, the event involved 'Cocktails, meeting, and dinner'.

In one attendee's description on Instagram, the 'Doctor's dinner start with a little bit of science'. Another attendee, wearing a cocktail dress, described the launch symposium using the hashtag '#fashionevent'.

The complainant alleged that the selected venue was obviously inappropriate for a launch symposium. Also, the extensive luxury hospitality provided alongside the Letybo launch symposium was also quite clearly disproportionate to the scientific content.

The complainant provided photos of the event.

When writing to Croma, the Authority asked it to consider the requirements of Clauses 2, 5.1 and 10.1 of the Code.

RESPONSE

Croma submitted that it was, at all times, in full compliance with applicable 'Good Promotional Practices' in all communication and interaction with its customers.

With regard to the specific complaint based on the Code, Croma highlighted that the event in Monaco was organised and hosted by Croma Pharma Austria, and therefore Austrian law (AMG) served as the legal foundation.

The hosting by Croma Pharma Austria comprised selection and payment of the venue, invitation, and registration of health professionals as well as the agenda and shared content. Croma's UK affiliate, Croma-Pharma Ltd, had no responsibilities whatsoever in this respect and did not sponsor any UK delegate.

The event itself was an international event with health professionals from various countries/territories that hosted 170 delegates in total.

Croma submitted that its UK affiliate of course complied with the Code and was currently finalising its membership application. Its affiliate had recently liaised with the Association of the British Pharmaceutical Industry (ABPI) about membership of the ABPI. Once this was done, Croma-Pharma Ltd would comply with the Code and accept the jurisdiction of the PMCPA.

Croma Austria was happy to respond to concerns brought up directly by the complainant. At the same time, Croma appreciated the Authority's understanding that, given the two paragraphs above, the company did not follow a deeper investigation.

Alleged inappropriate venue

The named aesthetics congress was an international event organised under the supervision of a named aesthetics society and had been held in Monaco for many years. There was a limited number of venues that could host large numbers of guests within a suitable distance to the congress. The named hotel was the only available venue providing a meeting room with this capacity, and within this location. Croma booked the least luxury room on -3 basement level. The event was explicitly for invited health professionals who signed in on arrival.

Alleged inappropriate hospitality ('Cocktails, Meeting & Dinner')

Croma agreed that the complainant correctly stated that the above was the signage of the hotel. Croma Austria was sorry that the hotel team independently took the liberty to give Croma's symposium a title of 'Cocktail, Meeting & Dinner', of course without being requested to do so by Croma. This was not aligned or approved. Croma would endeavour to be even more vigilant in the future.

Croma stated that it provided 90 minutes of high-class scientific and relevant content, delivered by internationally respected speakers (two named professors and two named doctors), followed by a 'Questions & Answers' session which closed with a dinner and wine. Cocktails were not served at any time. The company submitted that this was in-line with current guidelines and limits.

Alleged disproportionate scientific content (based on examples from social media)

Croma stated that it did not have any influence on what the health professionals posted on their social media, especially as it was an international event and each country had different rules. The health professionals whose postings were cited in the complaint were not UK health professionals but apparently from Romania and Poland; therefore, the language barrier regarding 'some little science' might be incorrectly interpreted. The UK affiliate team advised its UK customers not to post anything related to the brand name etc as these were the UK local regulations.

Croma stated that it could neither control content posted on social media, nor did the company introduce a hashtag #fashionevent.

The company stated that UK regulations might surely not be applied to a Polish doctor attending an event in Monaco that was held by an Austrian company like Croma.

Regarding appropriate dress, Croma did not, and could not, request a specific dress code for events. This health professional in question decided to wear a cocktail dress, based on their personal decision and taste.

Further information

Following receipt of the initial response, the company was asked by the Case Preparation Manager for more details about whether UK health professionals were invited by Croma Austria, if they attended the event and, if so, who paid for their attendance. The company was asked to provide details about the UK speaker and whether any UK staff attended and their role.

In response, Croma stated that for the international event in scope also health professionals from the UK were invited by the Austrian Headquarters and did attend the symposium. No payment was associated with the attendance of any delegate.

At the event itself, staff from Croma's UK affiliate, Croma-Pharma Ltd, were present and their role was to welcome health professionals from the UK and accompany these delegates throughout the evening.

Out of the four speakers at this event, the two leading and internationally respected experts were from the UK.

Following receipt of the second response, the company was asked by the Case Preparation Manager for comprehensive details about both the organisation and content of the meeting at issue.

In response, Croma stated that the hosting by Croma Pharma GmbH in Austria comprised of selection and payment of the venue, invitation, and registration of health professionals as well as the agenda and shared content and speakers. The UK affiliate, Croma-Pharma Ltd, had no involvement with the logistics and organisation of the event.

UK customers were not sponsored to attend the named aesthetics congress by Croma UK nor Croma AT. The company submitted that it therefore verbally invited UK customers that were present at the congress in Monaco to the scientific session and dinner. When speaking with customers, if they confirmed their own attendance at the congress, Croma submitted that it invited them at that time if they were interested to attend. Registration was then communicated internally with the company's global team and on arrival at the event room, delegates were asked to sign in to confirm their attendance.

In response to how the delegates were selected and invited Croma stated that the event itself was an international event with health professionals from various countries/territories that hosted 170 delegates in total. A list was provided. UK delegates were not sponsored to attend the named aesthetics congress but if attending the congress and appropriate for the session they were verbally invited.

The company provided copies of the global invitation (which Croma stated was not circulated to UK customers), agenda, a presentation by two named UK professors, a presentation by two senior global staff. Croma stated that there were 11 UK health professionals in attendance, 2 of whom were the speakers for Global.

Croma submitted that staff were given a verbal briefing *in situ* prior to the arrival of guests.

Croma submitted that Croma AT provided 90 minutes of high-class scientific and relevant content, delivered by internationally respected speakers. followed by a 'Questions & Answers' session which closed with a dinner and wine. The company stated that contrary to the complaint, cocktails were not served at any time. This was in-line with current guidelines and limits of £75 plus VAT plus Service charge. The costings for the dinner were provided. The company pointed out that exchange rates might differ now but were strictly within limits back in April 2022. Soft drinks were served on arrival. Once the scientific session was completed, dinner was served with wine, beer or soft drinks. Two UK delegates did not stay for the dinner, just for the scientific session.

Case AUTH/3694/10/22

In September 2022 the PMCPA received a complaint, forwarded by the MHRA, about the meeting at issue in Case AUTH/3644/5/22. The complaint was the same as the one sent to the PMCPA in May 2022. The MHRA asked the PMCPA to deal with the complaint. The MHRA was informed that a similar complaint had been received and that the PMCPA was dealing with it. The company was informed in October 2022.

PANEL RULING

The Panel noted that the Constitution and Procedure stated that the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. This ruling applied to both cases at issue.

The Panel noted that at the time of the symposium in question the company was neither a member of the ABPI nor was it on the list of non-member companies that had agreed to comply with the Code. It subsequently decided to join the list of non-member companies. In such circumstances, the Panel noted that it was not unusual for the event in question to have occurred before the company joined the list of non-member companies complying with the Code. Whether such cases fell to be considered was decided on a case-by-case basis. The Panel also bore in mind the long-established principle that if the subject matter of the complaint could very broadly be described as potentially a matter covered by legal requirements, such as hospitality or the provision of gifts, then the complaint would be considered in the usual way. The Panel noted the second complaint, Case AUTH/3694/10/22, had been referred to the PMCPA for consideration by the MHRA.

The Panel noted the role of Croma Pharma Austria in this matter. The Panel noted that it was established that a UK company was responsible for the acts or omissions of its overseas affiliates that came within the scope of the UK Code.

The first point the Panel had to consider was whether the subject matter of the complaint was within the scope of the Code.

Croma stated that the symposium was an international launch event and Croma Pharma Austria was responsible for the selection and payment of the venue, invitation, and registration of health professionals as well as the agenda and shared content. No payment was associated with the attendance of any delegate. The Panel noted the submission that the UK company, Croma-Pharma Ltd, had no responsibilities whatsoever in this respect and did not sponsor any UK delegate and that UK health professionals were verbally invited to the symposium/dinner at the Congress. UK staff were present at the symposium and their role was to welcome UK health professionals and accompany these delegates throughout the evening. The Panel noted that 11 UK health professionals attended the event including two speakers. In the Panel's view, that the UK staff's formal role at the meeting was to accompany UK health professionals throughout the event, meant that the UK company had a responsibility to ensure that the arrangements were appropriate for those delegates. In this regard, the Panel noted that the applicability of UK compliance requirements appeared to have been implicitly accepted by the company as the UK affiliate team instructed UK delegates not to post certain matters on social media due to local regulations.

The Panel noted Croma's response in relation to the event falling under Austrian jurisdiction, however, the Panel noted its comments above and decided that the combination of the verbal invitation and formal role of UK staff with UK delegates at the event meant that the

arrangements for the symposium, with regard to UK delegates, fell within the scope of the UK Code and ruled accordingly.

The Panel noted that the complainant's concerns related to the venue and hospitality alleging that 'extensive luxury hospitality' provided was disproportionate to the scientific content.

The Panel noted the complainant's allegation that the venue was inappropriate for a launch symposium and referred to it as a luxury five-star venue and a member of the leading hotels of the world group. The Panel noted Croma's submission that the named aesthetics congress was an international event organised under the supervision of the named aesthetics society and had been held in Monaco for many years. The Panel noted the company's response that the named luxury hotel was selected for the symposium based on the limited availability of sufficiently sized meeting space during the Congress.

The Panel noted the requirements of Clause 10.1 in relation to meetings including, amongst other things, that:

- the event/meeting must have a clear educational content; it should be the programme that attracts delegates to attend and not the associated hospitality or venue
- the venue must be appropriate and conducive to the main purpose of the event/meeting; lavish, extravagant or deluxe venues must not be used
- any associated subsistence (food and drink), accommodation and travel costs must be strictly limited to the main purpose of the event/meeting, must be of secondary consideration and must be appropriate and not out of proportion to the occasion
- companies must not sponsor, support or organise entertainment (such as sporting or leisure activities, etc).

The Panel noted that the supplementary information to Clause 10.1 stated that the impression that is created by the arrangements must be borne in mind.

The Panel noted Croma's submission about the limited number of venues for the symposium but, nonetheless, noted that it appeared that other venues were available, albeit not many. The Panel noted that the Code did not prohibit the use of five-star hotels *per se*. Some companies' own codes and policies prevented use of such hotels. Nonetheless, the impression given by the use of a prestigious five-star hotel in Monaco was particularly relevant. Whilst noting Croma's submission that the event was held in the 'least luxury room', the Panel considered that, from the delegates' perspective, the room was an integral part of a 5-star Monaco-based hotel. The Panel considered that the impression created by the use of a five-star Monaco-based hotel for the launch symposium was inappropriate and delegates might have been attracted by the venue rather than the educational content.

The Panel noted that Croma agreed with the complainant that the signage stated 'Cocktails, Meeting & Dinner' and explained that this was independently placed by the hotel rather than the company. The Panel noted that Croma stated this was not aligned or approved and that soft drinks were served on arrival.

The Panel considered that Croma may, to a degree, have been let down by the hotel but noted that it was the company's responsibility to ensure that matters such as signage were Code

compliant. It was good practice to agree such matters prior to a meeting and to check and, if necessary, remove/alter signage prior to the start of a meeting. The Panel considered that the word 'Cocktails' gave a very poor initial impression. Some delegates and others who saw the signage might consider that the event was, in part, a social event.

The Panel noted Croma's submission about the social media posts. Croma stated that it could neither control content posted on social media, nor did the company introduce a hashtag #fashionevent. The Panel noted that UK delegates had been told by the UK team not to post in relation to the brand name etc due to local regulations and thus it appeared clear that, at the very least, posting was an activity that the company foresaw delegates might engage in. The Panel considered, however, that the complainant had not complained about the social media posts *per se* but had referred to them as evidence of the impression created by the event.

The Panel noted that the clinical part of the meeting was held between 6.30pm and 8pm and comprised of an introduction and 3 clinical presentations. Croma submitted that the clinical sessions lasted for 90 minutes followed by a 'Questions & Answers' session. Dinner began at 8pm and the event finished at 10pm. No cocktails were served but wine, beer or a soft drink were provided with the evening meal which Croma submitted was within current guidelines and the £75 plus VAT limit. A partially redacted copy of the invoice was provided. The Panel was concerned that Croma made no submission in relation to the supplementary information to Clause 10.7 in relation to the financial threshold when an event was held outside the UK in a European country where the national association was a member of EFPIA. The position was unclear in this regard.

Overall, and irrespective of the lack of clarity around the financial expenditure referred to above, the Panel considered that the impression created by the arrangements was such that hospitality, including the venue, did not appear to be secondary to the main purpose of the event, the five-star Monaco-based venue was inappropriate and delegates might have been attracted to attend by matters other than the scientific content. This was, in the Panel's view, compounded by the poor impression created by the signage and reference to 'cocktails'. **A breach of Clause 10.1** was ruled. The Panel considered that, overall, high standards had not been maintained, **a breach of Clause 5.1** was ruled.

The Panel noted that Clause 2 was reserved for use as a sign of particular censure which, according to its supplementary information, included matters of excessive hospitality. The Panel noted that the hospitality provided, in particular at international meetings, attracted public scrutiny and given the poor impression created by the arrangements, considered, on balance, that Croma had brought discredit to, and reduced confidence in, the pharmaceutical industry. **A breach of Clause 2** was ruled.

Complaint received **10 May 2022**

Case completed **8 June 2023**