CASE/0892/03/26

COMPLAINANT v ALLERGAN

Allegations regarding pre-licence promotion at a dermatology congress

CASE SUMMARY

This case was in relation to an Allergan booth at a dermatology congress held in France in January 2026. The complainant alleged that a screen on the company's booth promoted BoNT-E (trenibotulinumtoxinE) prior to the grant of its marketing authorisation and that, when asked about the product by the complainant, an Allergan representative from the UK had explained its mode of action and intended use without stating that it was not yet licensed. The complainant further alleged that the booth should have complied with the ABPI Code because it included UK particulars and was staffed by UK personnel.

The outcome under the 2024 Code was:

Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 8.1	**Failing to certify promotional material (the medical booth)**
Breach of Clause 11.1	**Promoting a medicine prior to the grant of its marketing authorisation**

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 8.1	**Requirement to certify promotional material (the commercial booth)**
No Breach of Clause 11.1	**Requirement that a medicine must not be promoted prior to the grant of its marketing authorisation**
No Breach of Clause 17.1	**Requirement that representatives must be given adequate training and have sufficient scientific knowledge to enable them to provide full and accurate information about the medicines which they promote**

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 Allergan Ltd was received from a contactable complainant who described themselves as a healthcare professional.

COMPLAINT

The complaint wording is reproduced below:

> "Hi pmcpa complaints department.
>
> I attended IMCAS which is a dermatology congress in Paris last month. On the congress Allergan botox booth, which clearly had the MHRA adverse event reporting statement and also the UK PI available via a QR code. I assumed this sales booth had undergone thorough rigor of UK approval before being finalised.
>
> However, I was shocked to see the pre licence promotion of their upcoming POM bont-E on a screen on one side of the sales booth. Bont-e is a toxin which is not yet licenced anywhere in Europe. Having it clearly displayed on the screen is evidently inviting questions around it and cannot be anything but pre label promotion.
>
> I understand that it is a French congress but having the uk particulars like MHRA box, uk PI, UK personnel working on the sales booth means it should all abide by the UK rules.
>
> When asked about it, the rep explained the mode of action and what it would be used to treat. At no point did anyone mention to me that is it not available or licenced yet.
>
> I would appreciate if you pulled up allergan on this matter
>
> Thanks
>
> I do not work for allergan. Nor have I worked for allergan. I dont have shares in the company. I am a health care professional."

When writing to Allergan, the PMCPA asked it to consider the requirements of Clauses 2, 5.1, 8.1, 11.1 and 17.1 of the 2024 Code.

ALLERGAN'S RESPONSE

The response from Allergan is reproduced below:

> "Thank you for your letter dated 6th March 2026 regarding a complaint received by the PMCPA related to concerns about company activities at IMCAS congress in Paris on 29th-31st January 2026.
>
> Allergan Aesthetics, an AbbVie company, takes our responsibility for compliance with all applicable laws and regulations including the ABPI Code of Practice ('the ABPI Code') very seriously and we continuously endeavor to maintain these high standards in all our activities at all times.
>
> In the remainder of the response, we will refer to 'Allergan', in reference to Allergan Aesthetics, an AbbVie company.
>
> **Complaint**

The complainant, who identified themselves as an HCP, has expressed concern regarding materials and a discussion around BoNT/-E at the IMCAS congress in Paris in January 2026. The Case Manager has requested Allergan to consider the requirements of Clauses 2, 5.1, 8.1, 11.1 and 17.1 of the 2024 ABPI Code in our response.

BoNT/-E
TrenibotulinumtoxinE (BoNT-E) is an Allergan product that, at time of complaint, is undergoing EU regulatory assessment. The UK application is not yet submitted with the MHRA. It is expected to be filed this year.

Congress information
IMCAS Paris is one of a series of international medical research congresses focused on providing physicians (plastic surgeons, dermatologists and medical aesthetic practitioners) with the latest scientific updates for their professional progress in the plastic surgery, dermatology and aging science fields. Experts from around the world can choose to attend this congress. The congress is not organised by Allergan.

Allergan at IMCAS Paris 2026
Allergan Pharmaceutical International Limited, which is not a UK entity, sponsored this congress and as part of this sponsorship had booths at IMCAS. The booth presence was a commercial booth with a separate medical booth, which was positioned around the back of the commercial booth. Both booths, through visual separation and booth design distinctiveness, were strictly separated and distinct in both content and management perspective.

The commercial activities and materials were managed by the Allergan International Marketing and Commercial Operations ('IMCO') department who are headquartered in the UK. As such materials related to their activities were approved under both French and UK Codes. In this context, the UK PI was available on the commercial booth upon request and, as the congress was in France, QR codes were linked to Vistabel® only, which is the aesthetics presentation for Botulinum Toxin Type A in France*.

The medical activities and materials were managed by the Allergan Global Aesthetics Medical Affairs ('GAMA') department who are headquartered in US. As this event was held in France, the materials were approved under the French Code, in line with the Allergan Global SOP on Scientific Booths. This SOP includes:

- the expectations for distinction from commercial booths, through physical and visual separation and booth design distinctiveness, with recognition that physical separation may not be possible in all congress venues. At IMCAS, it was not possible to have physical distance between the commercial and medical booth, however there was visual separation and booth design distinctiveness.
- the expectation that approval should be in line with applicable SOPs and rules in the country or locale where the booth is being placed.

Allergan concluded that the image shared by the complainant was from the medical booth only.

The medical materials on the medical booth were not approved under the UK ABPI Code as the event was not intended for a UK audience. The congress was taking place in France and Allergan (IMCO, GAMA or the UK affiliate) did not invite or support any UK HCP to attend IMCAS in Paris, nor were any UK HCP contracted to perform any service on behalf of Allergan at the congress. Additionally, the congress was sponsored by a non-UK Allergan entity. Therefore, in Allergan's view, the medical activities and materials, including the booth materials alluded to in this complaint, were outside of the scope of the UK ABPI Code.

Regrettably, during the investigation into this complaint, Allergan did identify that two members of the UK medical team were present at the booth, which resulted in a single interaction where a member of the UK medical team responded reactively to a question regarding BoNT/E, from 2 UK HCPs.

Response

We would like to take this opportunity to address the concerns raised by the complainant in relation to the following clauses:

Clause 8.1 Promotional material certification

Clause 8.1 of the ABPI Code stipulates that 'promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified by one person on behalf of the company in the manner provided for by this clause, subject to the provisions of the supplementary information to this clause where relevant. This person must be a registered medical practitioner or a pharmacist registered in the UK or alternatively, in the case of a product for dental use only, a UK registered dentist. The person certifying on behalf of the company must not be the person responsible for developing or drawing up the material.'

Allergan is of the view that this clause is not applicable as the materials relating to this complaint are medical materials subject to approval under the French Code and were consequently not promotional materials as defined under the ABPI Code.

On this basis Allergan respectfully refutes a breach of Clause 8.1 of the ABPI Code.

Clause 11.1 Promotion of medicine prior to Marketing Authorisation

Clause 11.1 of the ABPI Code stipulates that 'a medicine must not be promoted prior to the grant of the marketing authorisation which permits its sale or supply subject to the provisions of Clause 11.3 below.'

The single interaction with 2 UK HCPs identified is related to a reactive response to a HCP's question by a member of Allergan's medical team. Our investigation has revealed that there was no proactive communication of pre-license information by any promotional, commercial, medical or other Allergan team. The information provided reactively was of a scientific, non-promotional nature and therefore Allergan is of the view that there was no promotion prior to the grant of the Marketing Authorisation.

On this basis Allergan respectfully refutes a breach of Clause 11.1 of the ABPI Code.

Clause 17.1 Representatives training and knowledge of medicines they promote

Clause 17.1 of the ABPI Code stipulates that 'representatives must be given adequate training and have sufficient scientific knowledge to enable them to provide full and accurate information about the medicines which they promote.'
Clause 1.19 of the ABPI Code further defines a 'Representative' as one 'calling on members of the health professions and other relevant decision makers in relation to the promotion of medicines'.

Allergan takes the training of its representatives very seriously, however, does not believe that this clause is applicable to this case. The Allergan medical booth was non-promotional in nature and was manned by members of the medical affairs department only. There were no members of promotional or commercial teams present at the medical booth and consequently, there were no Allergan sales representatives present at the medical booth.

On this basis Allergan respectfully refutes a breach of Clause 17.1 of the ABPI Code.

Clause 5.1 High Standards

Clause 5.1 of the ABPI Code stipulates that 'companies must maintain high standards at all times'.

As indicated above, the Allergan medical booth was managed by the GAMA department and, as this congress took place in France, was approved under the French Code. However, Allergan did identify that two members of the Allergan UK affiliate medical affairs team at IMCAS did attend the medical booth and, during this time, one of them did have a single engagement with two UK HCPs. The UK HCPs asked for information on BoNT/E and in response, they discussed the mechanism of action. Our investigation revealed that the medical team member did make it clear that the product was not licensed in the EU or UK nor was it available for use. Allergan did not identify any other evidence or recollection of any discussion with any other UK HCPs.

While the medical booth was approved under French Code as the congress was in France, Allergan does recognise this one instance where a member of the Allergan UK medical team reactively responded to a question from two UK HCPs regarding a pre-license product. While approved under the French Code, the product name and mechanism of action material were available on the medical booth, as such Allergan acknowledges that Allergan UK medical team members should not have been present at the medical booth because the booth materials were not approved under the ABPI Code. On this basis, Allergan acknowledges a breach of Clause 5.1 as this error is not in line with the high standards that Allergan endeavors to maintain at all times.

Actions taken and further planned CAPA

Allergan are committed to maintaining high standards at all times and have already implemented actions to ensure this is not repeated. Allergan also commits to assess opportunities for continual improvement. Allergan can confirm that both UK colleagues who attended the congress have completed all ABPI and SOP training assigned to

them and have been retrained on the relevant SOPs as a refresher. Additionally, the wider UK medical team have received a reminder on the importance of following ABPI Code even when at congress outside UK and that no member of the UK medical team attends global activities unless they are approved under the ABPI Code.

Additional CAPAs planned to prevent potential future re-occurrence:

- Learnings from the investigation into this Code complaint will be shared with the UK medical team at the next medical meeting in April. In addition to sharing this Code complaint, it will be combined with refresher training on activities at international congresses including a focus on interactions with HCPs and reactive responses to enquiries, specifically pre or off license questions.
- GAMA have been informed that UK medical colleagues cannot attend any activities at any future congresses unless it is approved in line with the ABPI Code.
- As part of continual improvement, a review of all applicable SOPs will be undertaken to assess opportunities to reinforce the learnings, additional guardrails will be put in place, and all relevant teams will subsequently be retrained on the new versions of the SOPs.
- The information, outcome and learnings from investigation into this complaint will be shared and discussed with the UK and International Compliance Forums to ensure company leadership are aware of the case and cascade the key learnings to their teams to prevent similar breaches of the Code from occurring again.

While Allergan believe the medical materials and activities at IMCAS were outside of the scope of the ABPI Code, Allergan fully reviewed the approvals under the French Code during our investigation into this case and, in the interest of full transparency and collaboration with the PMCPA, we identified a single missing approval, which GAMA are also addressing by putting in place additional guardrails to ensure instances like this cannot occur again.

Clause 2 Upholding confidence in the industry

Clause 2 of the ABPI Code stipulates that ‘activities or materials must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry.’

While Allergan acknowledges that two UK Allergan medical team members should not have been present at the medical booth and further, in an isolated instance, one of these UK Allergan medical team members should not have reactively responded to a question on a pre-licensed product from two UK HCPs, our in-depth investigation has not revealed any evidence suggesting these constitute a systematic issue. The inquiry demonstrated that during their interaction, our medical team member clearly communicated to the UK HCPs that the product in question is not licensed in EU or UK and is not available for use. As a result, in our view there is no basis to conclude that there was promotion prior to the grant of a marketing authorisation or that patient safety was compromised.

Allergan fully recognises that, in this instance, its actions fell short of the rigorous standards of conduct to which it holds itself accountable. In response to this, and as

soon as the issue was identified, Allergan already took a number of measures to prevent any recurrence. In addition, a range of further CAPAs are planned to reinforce these safeguards and continually elevate our standards.

Accordingly, Allergan maintains that this isolated matter is not of nature that would bring discredit upon, or diminish confidence in, the pharmaceutical industry, and therefore, we believe that Clause 2 of the ABPI Code was not breached.

Summary
In summary as outlined above, Allergan does not believe that the activities relating to IMCAS 2026 in Paris has breached Clauses 8.1, 11.1, 17.1 or 2 of the ABPI Code. Allergan accepts that the single instance of a reactive response with two UK HCPs did result, inadvertently, in pre-license discussion of BoNT/E and combined with UK medical presence on the booth accept a breach of Clause 5.1.

As indicated in our response, actions have already been taken to highlight this with the UK medical team as part of immediate learning with the following CAPAs to prevent recurrence:

- Learnings from the investigation into this Code complaint will be shared with the UK medical team at the next medical meeting in April. In addition to sharing this Code complaint, it will be combined with refresher training on activities at international congresses including a focus on interactions with HCPs and reactive responses to enquiries, specifically pre or off license questions.
- GAMA have been informed that UK medical colleagues cannot attend any activities at any future congresses unless it is approved in line with the ABPI Code.
- As part of continual improvement, a review of all applicable SOPs will be undertaken to assess opportunities to reinforce the learnings, additional guardrails will be put in place, and all relevant teams will subsequently be retrained on the new versions of the SOPs.
- The information, outcome and learnings from investigation into this complaint will be shared and discussed with the UK and International Compliance Forums to ensure company leadership are aware of the case and cascade the key learnings to their teams to prevent similar breaches of the Code from occurring again.

As the relevant materials and activities relate to the medical booth and materials approved under French Codes, the approver is not an ABPI signatory and have therefore not provided this information

We reiterate our continued commitment to operating consistently with the highest standards and in compliance with all applicable laws, regulations and the ABPI Code.

Allergan thanks the PMPCA for the opportunity to respond to this complaint. We remain available to answer any further questions you may have.

*UK was originally part of the EU Marketing Authorisation (MA) (agreed under EU Mutual Recognition Procedure) for Vistabel® approved in EU in 2006. An internal commercial decision in UK to consolidate both the therapeutic and aesthetic indications

under the Botox® Marketing Authorisation in UK was taken in consultation with the MHRA. The UK Vistabel® MA was withdrawn from UK market in March 2019."

FURTHER INFORMATION FROM ALLERGAN

Further information was provided by Allergan following a request from the case preparation manager. The response from Allergan is reproduced below:

"Thank you for reaching out, in response to your request for additional information related to this code case, please find the below data:

1. Further details as to how the screen was used. For example, could users swipe through the different screens themselves? Please can you confirm what happens should a user click through to the interactive activity or video on screen 10.
    - The screen could not be used directly by an HCP to swipe through by themselves, it was operated by local country affiliate members of the wider Global Aesthetics Medical Affairs ("GAMA") team only, who always staffed the booth to respond reactively to any questions.
    - The screen options for BoNT/E at IMCAS was as follows:
        - BoNT-E Mechanism of Action
        - BoNT-E MOA Video (From our investigation it was confirmed by [a member of the global medical team] that the video was not on a loop and only used when required).
        - The BoNT-E This or That Interactive Activity did not work and was disabled for IMCAS

Therefore, there was no interactive activity available on the booth for users to access.

2. copies of any briefing materials and instructions given to employees manning the booth, including any verbal instructions given
    - On 26th Jan 26, [a member of the global medical team] briefed the wider local country affiliate GAMA teams attending the IMCAS congress, who were going to be staffing the medical booth.
        - For completeness and as per our original response dated 2nd April 2026, the medical booth activities were managed by the Allergan GAMA global department who are headquartered in US. As this event was held in France, the materials were approved under the French Code, in line with the Allergan Global SOP on Scientific Booths. For this reason, this document was not examined under the UK code nor was it formally approved as it was classified as an internal communication developed by the global GAMA team.
    - On day 1 of the congress, all GAMA team members staffing the medical booth were invited by [a member of the global medical team] to attend a walk round of the medical booth, it was at 8.30am (Paris time) on 29th Jan 26. If anyone could not attend, they received a personal walk though at a time suitable and prior to taking up their booth activities.
        - The walkthrough provided an overview of the booth setup and operational arrangements, including the functionality of the touch screens to support reactively responding to HCP unsolicited questions, the use of the medical information QR code, and the demonstration of filler rheology using the microscope."

FURTHER INFORMATION FROM ALLERGAN

Further information was provided by Allergan following a request from the Panel. The response from Allergan is reproduced below:

"In response to your request for additional information regarding this Case/0892/03/26, please find our responses to the points raised below.

1. **Visuals of the 2026 IMCAS Allergan booth showing the Medical and Commercial booths**

Please see the attached approved IMCAS booth job bag, which includes the graphics showing the 2026 IMCAS Allergan commercial booth and the location of the medical booth in relation to it.

As provided in our response on 2nd April 2026, although it was not possible at IMCAS to have physical distance of location between the commercial and medical booth, we ensured that they were separated by stand panels/walls, visual separation, booth design distinctiveness and management perspective, in line with the Allergan Global SOP on Scientific Booths.

2. **Commercial booth design and its associated UK approval certificate.**

Please see the attached approved job bag, which includes the graphics for the commercial booth design, together with the approved certificate. The UK signatory for the booth was [signatory details].

In addition, please find attached an Excel file listing the job bags that relate to the content of the booth panels and for the "Meet the Experts" series. Please let us know if you would like us to provide you with any of these materials.
In relation to the approval certificate, Veeva PromoMats generated a certificate in French. This occurred because the job bag was created for two affiliates, "Global" and "France":

- "Global" in job bags indicates content created by the Allergan International Marketing and Commercial Operations ("IMCO") department, which is headquartered in the UK and requires approval under the UK ABPI Code. We confirm this job was certified under the UK Code and signed by a validated UK signatory nominated to the PMCPA and MHRA on behalf of Allergan Aesthetics, an AbbVie company.
- As the conference took place in France, approval under the French Code was also completed by a member of the French Allergan affiliate within the same job bag.

We are currently actively working on a technical solution to ensure an English certificate is generated in future cases. In the interim, metadata for any such jobs will confirm that the relevant jobs are approved under the ABPI Code.

3. **Clarification on the role of the UK medical team members with respect to the medical booth - were they formally 'manning' the booth e.g. on the rota or just present on a temporary/adhoc basis? Please can you clarify the reason they were available to answer questions from HCPs?**

Of the two UK affiliate members who were available at the booth, their roles were as follows:

- One member of the UK affiliate was on the rota manning the booth on Friday 30th January 2026 from 1pm to 6pm.
- One member of the UK affiliate was on the rota as "check in" on Friday 30th January 2026 from 1pm to 6pm. This role was to check in with the booth team during this time frame to offer any additional support including answering reactive requests from HCPs, as required.

As per our response on 2nd April 2026, Allergan acknowledges that Allergan UK medical team members should not have been present at the medical booth because the booth materials were not approved under the ABPI Code. On this basis, Allergan acknowledged a breach of Clause 5.1 of the ABPI Code as this isolated error is not in line with the high standards that Allergan endeavours to maintain at all times.

Allergan are committed to maintaining high standards at all times and would like to take this opportunity to reassure the PMCPA that we have already implemented actions to prevent potential future re-occurrence:

- In addition to self-learning on relevant SOPs, the UK Medical Affairs team received training on 26 April 2026. The session used this Code Case to support learning and included discussion of applicable SOP self-learning questions relating to congress booths and interactions with external stakeholders. The session was delivered by [details of training provided].
- Allergan took appropriate steps to reinforce to the Global Medical Affairs team that UK Medical Affairs Affiliate team members cannot attend any activities unless they are approved under the UK code.
- The local meetings SOP has been updated to reinforce the learnings from this Code Case. The updated SOP was rolled out to the UK affiliate in April 2026 for self-learning and training completion, supported by optional drop-in sessions in April and May 2026 for questions on the changes, led by [a member of the compliance team].
- The information was shared at the relevant leadership meetings which includes an audience of key commercial, medical and compliance personnel with the UK (16 April 2026) and EU Compliance Forum (5 May 2026) to support wider leadership awareness and continual improvement.

In addition to the above actions, and as part of the company's commitment to continuously endeavour to maintain high standards across all our activities, the International Regulatory Review team, i.e. the signatory team, allocated an additional resource to support the Allergan Global Aesthetics Medical Affairs ("GAMA") team. This support will include guidance on international conferences, including materials, briefings, symposiums, and related activities. The individual in this role is [details of UK signatory experience].

4. **Did the UK Medical Affairs colleagues attend the medical booth briefing and what instructions were they provided (if any) about representing the company at the medical booth?**

We can confirm that both members of the UK Medical Affairs team attended the virtual medical briefing on 26 January 2026 and the on-booth briefing on the morning of 29 January 2026.
Instructions on how to represent the company were covered during the 26 January 2026 briefing, in line with the briefing document shared in April 2026.

Allergan Aesthetics takes its responsibility for compliance with the ABPI Code very seriously and remains available to answer any further questions you may have."

PANEL RULING

This case was in relation to an Allergan-sponsored exhibition booth at a dermatology congress in Paris, in January 2026. The complainant stated that whilst the booth contained UK prescribing information and an MHRA adverse event reporting statement, they alleged it also featured pre-licence promotion of Allergan's upcoming prescription-only medicine "BoNT-E" on one side of the booth. The complainant further alleged that when asking an Allergan representative about the product, the representative explained the mode of action and what it would be used to treat, but at no point was it mentioned that the product was not available or licensed yet.

Allergan submitted that Allergan Pharmaceutical International Limited, a non-UK entity, had sponsored the congress and that its booth presence was comprised of a commercial booth with a separate medical booth positioned at the back of the commercial booth. Allergan had concluded that the image provided by the complainant which referred to BoNT-E was from the medical booth only.

Medical Booth

In addition to their allegation about pre-licence promotion as outlined above, the complainant further reasoned that whilst it was a French congress "having the UK particulars like MHRA box, PI [prescribing information], UK personnel working on the sales booth means it should all abide by the UK rules".

Allergan submitted that the commercial and medical booth were strictly separated and distinct from both a content and management perspective. Allergan stated that as the commercial activities and materials at the congress had been managed by a UK headquartered department, these materials including the commercial booth had been approved under both the French and UK Code and that it was within this context that UK prescribing information was available on the commercial booth upon request. In contrast, the medical activities and materials at the congress were managed by a US headquartered department. Consequently, Allergan submitted these materials, including the medical booth, were approved under the French Code only, in line with its internal SOP.

As the congress had taken place in France, had been sponsored by a non-UK Allergan entity, was not intended for a UK audience, and Allergan had not invited or supported any UK health professional to attend, Allergan submitted that the medical activities and materials, including the medical booth, were outside the scope of the UK ABPI Code.

Allergan did submit, however, that two members of its UK medical team were present on the medical booth which resulted in a single interaction with two UK health professionals where a member of the UK medical team responded reactively to a question regarding BoNT-E.

The first matter for the Panel to determine was whether the medical booth was in scope of the UK ABPI Code.

Allergan submitted that one member of the UK affiliate had been on the rota to man the medical booth for five hours, and that a second member of the UK affiliate was on the rota as "check in" for the same time slot, to "offer any additional support including answering reactive requests

from HCPs as required". Allergan acknowledged that UK medical team members should not have been present at the medical booth as the booth materials had not been approved under the ABPI Code. It acknowledged a breach of Clause 5.1 in respect of this. Allergan accepted that, during the UK medical team's presence on the booth, an interaction between them and two UK health professionals regarding BoNT-E had taken place.

The Panel noted that the commercial booth appeared substantial in size and the medical booth was situated at the back of the commercial booth. There was no physical distance between the two, albeit there appeared to be a wall separating the commercial and medical booth and a difference in colour. The Panel considered that the close proximity of a substantial commercial booth containing UK obligatory information to the medical booth may have given the impression to attendees that the medical booth was also applicable for a UK audience. To this point, the Panel noted that it appeared that the complainant had not been able to distinguish between the different areas and had referred to the medical booth as a "sales booth". This impression would have further been compounded by having UK medical staff manning the medical booth, and an interaction between UK Allergan staff and UK health professionals had in fact occurred on the medical booth. The Panel could not understand how Allergan could have expected UK medical staff to man the medical booth without referring to, or being seen to use, materials available or displayed on the booth.

Taking all the above into account, the Panel considered that, on balance, the medical booth had been brought into scope of the UK ABPI Code.

The Panel then had to determine whether the medical booth featured pre-licence promotion of BoNT-E.

Clause 11.1 of the Code stated that a medicine must not be promoted prior to the grant of the marketing authorisation which permits its sale or supply.

The image provided by the complainant appeared to be a photo of a slide which solely featured three bullet points stating:

- "BoNT-E Mechanism of Action
- BoNT-E This or That Interactive Activity
- BoNT-E MOA Video"

Allergan submitted that trenibotulinumtoxinE (BoNT-E) was undergoing EU regulatory assessment at the time of the complaint, and that no UK application to the MHRA had been submitted.

Allergan provided a full copy of the touchscreen menu available on the medical booth, which featured the slide captured as an image by the complainant. Allergan submitted that the screen could not be used directly by a health professional themselves and instead was operated by the staff manning the medical booth.

Based on the medical booth design, it appeared to the Panel that this touchscreen, and hence the slide featuring BoNT-E, would have appeared on a prominent screen at the back of the medical booth and would therefore have drawn the attention of a viewer visiting or walking past the booth, as it appeared to have done with the complainant. There was no indication on the slide that this product was still in development. Whilst the Panel acknowledged that the slide contained limited information, and did not include any claims or an indication, the Panel

considered that within the broad definition of promotion, prominently displaying the name of a new toxin alongside references to learn more about the mechanism of action, at a specialist dermatology congress was likely to solicit enquiries about this new unlicensed product, as alleged by the complainant. The Panel, therefore, concluded on balance that the medical booth promoted a medicine prior to the grant of a marketing authorisation and ruled a **breach of Clause 11.1**.

Interaction with the "rep"

The complainant alleged that when asked about BoNT-E, "the rep explained the mode of action and what it would be used to treat. At no point did anyone mention to me that is it [sic] not available or licensed yet".

Allergan submitted that the single interaction it had identified between UK medical staff manning the booth and two UK health professionals was a reactive response to a question from the health professionals regarding BoNT-E. Allergan submitted that the information provided was regarding the mechanism of action, and was of a scientific and non-promotional nature, and therefore denied a breach of Clause 11.1. Allergan further submitted that the UK medical team member did make it clear that the product was not licensed in the EU or UK.

The Panel considered, on the balance of probabilities, that the "rep" referred to in the complaint was a UK medical employee manning the medical booth who, as accepted by Allergan, had engaged in an interaction with two UK health professionals regarding BoNT-E. The Panel noted that the parties' accounts differed; it was difficult in such cases to know exactly what had transpired. The Panel had to make a judgement on the available evidence. The Panel decided it was not possible to determine what had been said verbally during the alleged interaction and considered it had not been established that a UK medical employee had promoted BoNT-E prior to the grant of a marketing authorisation and ruled **no breach of Clause 11.1**.

The Panel noted that Clause 17.1 of the Code had been raised by the case preparation manager. The Panel did not consider that the complainant had made a specific allegation in relation to this clause, nor had it been demonstrated that the UK medical employee met the definition of a representative as outlined in the ABPI Code. The Panel therefore ruled **no breach of Clause 17.1**.

Approval of booth

The complainant stated that they "assumed this sales booth had undergone thorough rigor of UK approval before being finalised".

Allergan submitted that the commercial activities and materials were approved under both the French and UK Codes and that the medical materials relating to this complaint were subject to approval under the French Code and were consequently not promotional materials as defined under the ABPI Code.

Allergan had provided a copy of the electronic certification of the commercial booth. The Panel noted that, whilst the certificate wording was in French, it had been approved by a UK signatory. The Panel, therefore, ruled **no breach of Clause 8.1** with respect to the commercial booth.

Having determined that the medical booth was in scope of the ABPI Code and that it promoted an Allergan medicine, the Panel noted that the Code required promotional material to be certified and, on that basis, ruled a **breach of Clause 8.1** with respect to the medical booth.

Overall

The Panel was concerned that Allergan had failed to recognise that scheduling UK employees to man the medical booth may bring the booth within scope of the ABPI Code. Although Allergan submitted that both of its UK medical employees had attended a virtual briefing and an on-booth briefing, Allergan was not able to demonstrate that these employees had been briefed on how to handle enquiries received from UK health professionals whilst manning the booth. This was concerning to the Panel as none of the booth materials had been approved under the UK ABPI Code. The Panel had concluded that Allergan had promoted a medicine prior to the grant of its marketing authorisation as a consequence of the medical booth being in scope of the UK Code. Allergan had therefore failed to maintain high standards and **a breach of Clause 5.1** was ruled.

Clause 2 was a sign of particular censure and reserved for such use. Whilst promotion prior to the grant of a marketing authorisation was listed as an example of an activity likely to be ruled in breach of Clause 2 (in the supplementary information to that clause), the Panel took into account the particular circumstances of this case: Allergan did not appear in any way to have directed UK health professionals to the medical booth. The Panel also considered that the limited information provided about BoNT-E on the medical booth was unlikely to prejudice patient safety. The Panel therefore did not consider that the circumstances of this case were such that Allergan had brought discredit upon, or reduced confidence in, the pharmaceutical industry. The ruling of a breach of Clause 5.1 was sufficient to address the Panel's concerns, and the Panel therefore ruled **no breach of Clause 2**.

Complaint received **27 February 2026**

Case completed **5 October 2026**