

Case AUTH/3786/6/23

COMPLAINANT v ABBVIE

Alleged promotion of Botox on a national television show

CASE SUMMARY

This case was in relation to the appearance of an AbbVie senior global medical affairs employee, based in the United Kingdom, on a popular national television quiz show. The complainant's allegations broadly related to the promotion of a prescription only medicine to the public and a breach of undertaking.

The outcome under the 2021 Code was:

Breach of Clause 5.1	Failing to maintain high standards
Breach of Clause 5.2	Failing to recognise the special nature of medicines
Breach of Clause 26.1	Promoting a prescription only medicine to the public

No Breach of Clause 2 (x2)	Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry
No Breach of Clause 3.3	Requirement to comply with an undertaking
No Breach of Clause 5.1	Requirement to maintain high standards
No Breach of Clause 8.1	Requirement to certify promotional material
No Breach of Clause 12.1	Requirement to include prescribing information
No Breach of Clause 12.3	Requirement to include the non-proprietary name
No Breach of Clause 12.9	Requirement to include the prominent adverse event reporting statement

**This summary is not intended to be read in isolation.
For full details, please see the full case report below.**

FULL CASE REPORT

A complaint was received from an anonymous, contactable complainant about AbbVie.

COMPLAINT

The complaint wording is reproduced below:

'I have recently come across a 2022 episode of the TV program [name], and as a Healthcare Professional, I am very concerned that the participation of a [senior global medical affairs employee] of a Pharmaceutical Company may have brought discredit upon the Pharmaceutical Industry.

Although the person concerned is free to take part in any tv show and not to hide their occupation, I am uncomfortable when they introduced themselves as “[job title] for a pharmaceutical and medical device company and predominantly [...] across the aesthetics franchise, so injectable products like Botox and facial fillers”.

This introduction unnecessarily mentions a prescription-only medicine as well as one of its potential areas of use (aesthetics) and does not reflect the special nature of this medication; this is of particular concern given this TV show has a regular audience of 3-5 million people and in my view should be considered a low standard of reckless promotion of a medicine to members of the public. The PMCPA has expressed clear views on this matter many times in the past and has stated that “whilst no indication was included [...] the indication of Botox was widely known, including to members of the public, and thus, in the Panel’s view, mention of Botox in itself was promotional.” (AUTH/3431/11/20); therefore, this new occurrence of a proactive use of such a known brand name could be a sign of deliberately ignoring previous undertakings by the company concerned (Allergan/AbbVie), and not operating in line with the high standards expected by a pharmaceutical company.

It is also worrying that a Senior Employee is involved, and I am wondering whether the employee concerned shared with their company their expected participation in this show and was consequently briefed accordingly on the expected behaviour during the show. The conduct of this senior employee was unacceptable particularly when one of the other contestants played a joke saying: “Well, my colleague [name] would like to place a large order for Botox please...her best potions needed”, to which they were smiling and nodding.

Moreover, given it is very likely that healthcare professionals would also be part of the 3-5 million people watching the episode, this repeated mention of a brand name would constitute promotion not only to members of public, but also to healthcare professionals. After watching the show, I have also noticed there was no mention of the generic name of the medicine, nor Prescribing Information or Adverse Events reporting information were provided (which I believe should be mandatory in prescription only medicines advertisement); I am therefore questioning whether this promotional activity was approved as expected by Allergan/AbbVie in advance.

In summary, I believe that the careless mention of a well known brand name by a senior employee of Allergan/AbbVie during a popular TV show constituted an unduly and reckless promotion to members of the public and to healthcare professionals, and trivialised a potent and dangerous treatment for many debilitating conditions. Such promotional activity, considering the involvement of a senior employee of Allergan/AbbVie was not in line with the requirements of the code and is a sign of failure to maintain high standards. Given the repeated mistakes involving a previously sanctioned company, this constitutes a breach of undertakings and consequently brings the whole Pharmaceutical Industry into disrepute.

Please note the episode is still available online on ITV, and the issue has also been the subject of an article on daily star’.

When writing to AbbVie, the Authority asked it to consider the requirements of Clauses 2, 3.3, 5.1, 5.2, 8.1, 12.1, 12.3, 12.9 and 26.1 of the Code.

ABBVIE'S RESPONSE

The response from AbbVie is reproduced below:

'Preliminarily, it is essential to emphasize that AbbVie are fully committed to strict adherence to the ABPI Code of Practice for the Pharmaceutical Industry ("**Code**") and all applicable laws and regulations. As a member of the ABPI, we are dedicated to applying high standards at all times across all areas of our business and we take any concern raised regarding compliance with the Code very seriously. Maintaining high standards is an important part of both the ABPI Code as well as AbbVie's Code of Business Conduct. All employees, upon joining the company, receive mandatory Code of Business Conduct training, which includes the requirement of all individuals to maintain high standards of conduct in the discharge of their responsibilities, as well as to follow all the laws, regulations, and industry codes applicable in the country in which they are based. Our Code of Business Conduct encourages open communication, respectful discussion, and a safe environment for all employee to "Speak-Up" and raise concerns freely.

Response:

AbbVie would like to reassure the PMCPA that the participation of the AbbVie employee named in the complaint ("Named Employee") at a national television show ("Show") was not an activity initiated, approved or directed by the company. We became aware of the participation of the Named Employee (a global medical affairs employee, based in the United Kingdom) in the Show on 4th May 2022, shortly after the Show aired on ITV on 29th April 2022, through a report raised by a UK-based AbbVie employee. The employee reported their concern directly to the local compliance officer, who together with HR immediately launched an internal investigation. This illustrates one of the ways AbbVie demonstrates its "Speak Up" culture and safe environment for employees to raise concerns internally.

During the investigation, the Named Employee explained that they did not communicate to AbbVie their intent to participate in the Show, nor did they seek any approval or guidance from AbbVie prior to their participation on the Show, as it related to their private/personal life having no relationship to their employment. They also explained that when they made the reference to BOTOX® on the Show, they did not plan or aim to promote a Prescription Only Medicine ("POM") to the general public, rather addressing a general question from the Show host around a brief description of their professional experience/background, which is commonly linked to all participants in the Show. As a result of the internal investigation, disciplinary action was taken with respect to the Named Employee, a sanction was applied and recorded in their HR file. Additionally, the following corrective actions were undertaken by the company:

1. Corrective discussion with the Manager of the individual:
The Named Employee was reminded by their manager of their responsibilities of maintaining high standards and continuously complying with the ABPI Code and the AbbVie Code of Business Conduct. Additionally, the discussion covered aspects related to the mention of BOTOX® on the Show potentially being

perceived as promotion of a POM to the public acknowledging that as per AUTH/3431/11/20 “The Panel noted... the indication of Botox was widely known, including to members of the public, and thus, in the Panel’s view, mention of Botox in itself was promotional.”. The employee was reminded that promotion of POMs to the general public is prohibited by AbbVie policies and the ABPI Code.

2. Sanction:
The Named Employee was sanctioned according to the outcome of the disciplinary action as a result of the internal investigation, in accordance with the applicable HR policies. The Named Employee accepted the sanction and did not appeal.
3. The Named Employee completed the An Introduction to the ABPI Code (2021 Edition) - Induction Training and Annual Refresher. This training reiterated that all employees must comply with the Code requirements: those who work in the UK business, those who support international and/or global functions but are based in the UK, and anyone who conducts activities in the UK or produces materials for or aimed at a UK audience. The training also highlights that employees need to comply with the Code when speaking to members of the public, such as friends and family. All AbbVie employees that work in the UK, including those supporting international or global functions, receive this training.
4. Named Employee was retrained on the AbbVie Code of Business Conduct: The AbbVie Code of Business Conduct is a guide that sets the high standards that all employees need to demonstrate at all times. The “Integrity in our Industry” section reminds employees to always follow laws and industry regulations and provides guidance on how to communicate with the public appropriately.
5. Communication of the incident to the Affiliate Compliance Insight Forum and Monthly Entity Compliance Meetings
Once the internal disciplinary investigation was completed, the case was discussed at the Affiliate Compliance Insight Forum and at the Monthly Entity Compliance Meeting to ensure company leadership were aware of the case and would cascade the key learnings to their teams to prevent similar breaches of the Code from occurring again.

Further planned corrective and preventative actions

We appreciate learning that the episode of the national TV Show remained available to the public through the ITV and Daily Star websites. On 14 July 2023, letters have been sent to ITV and Daily Star informing them that POMs cannot be advertised to the public and that maintaining the reference to BOTOX® in the episode could amount to a breach of Rule 12.12 of the CAP Code and the Human Medicines Regulations 2012 (HMRs), as applicable to ITV and Daily Star. We have requested both media outlets to take immediate action and remove all references to BOTOX® from their platforms, in particular the episode and article mentioned above.

In addition to the actions listed above, AbbVie are planning the following further

actions to be taken:

- Provided company communications on 24th July 2023 to all AbbVie employees residing in the UK or employed by the AbbVie UK affiliate to reiterate that there should be no mention of BOTOX® or any other POM to the public.
- Re-issued ABPI reminder training on 19th July 2023 for all AbbVie UK employees to reiterate that the Code applies to all UK-based employees, including all international and/or global teams that are based in the UK and may not be directly responsible or involved in activities related to the UK market. Continue to encourage employees to report their concerns through speak-up campaigns and training.
- Detailed presentations of the facts in the Case and further insights that can be embedded in current AbbVie practices and processes, to be delivered in key internal communications, forums and working groups, including:
 - The Entity Compliance Insights Forum on 4th September 2023; an AbbVie forum comprising of key members of the leadership teams across both our therapeutics and aesthetics divisions, that meets on a quarterly basis to discuss key developments in Code compliance and ensure the high standards of the Code are understood and followed consistently across all our business lines.
 - The AbbVie Code Club, an internal working group that meets fortnightly to discuss recently PMCPA published cases and the learnings that AbbVie can take from these, bringing together a broad audience including marketing, medical reviewers, company signatories and compliance functions from all business divisions.

Clauses 5.1 and 26.1 of the 2021 ABPI Code.

Whilst the intention of the Named Employee was not to promote a particular POM, AbbVie acknowledge that the manner in which they described their professional role on the Show included the mention of the BOTOX® name and this could be deemed as promotion in accordance with prior PMCPA cases, acknowledging that as per AUTH/3431/11/20 “*The Panel noted... the indication of Botox was widely known, including to members of the public, and thus, in the Panel’s view, mention of Botox in itself was promotional.*”. AbbVie was let down by the Named Employee in this case, and we accept that a breach of clause 26.1 of the Code has occurred. We were disappointed that the Named Employee failed to adhere to the high standards that we expect of all our employees, and in that we also accept that a breach of clause 5.1 of the Code has occurred.

Nevertheless, we are confident that this was a one-time incident, and this type of activity is not a systemic issue within the organisation. As previously noted, the decision to participate on this show rested solely with the Named Employee and related to their private/personal life having no relationship with their employment, with no awareness or involvement by AbbVie, while also noting that this one-time incident occurred on a national television show which is open to general participation and selection criteria hence making it unique and extremely unlikely

to have happened before or ever happening again. We also appreciate that another employee raised their concerns immediately following the company internal Speak Up processes, so the company was able to act swiftly, take corrective actions to effectively address this matter in a timely manner, and also take appropriate steps to ensure similar incidents do not occur again. This internal reporting behaviour underlines the effectiveness of AbbVie's Speak Up policy and culture, internal training programs, and is in line with the ABPI principles of self-regulation.

Clause 2

AbbVie did not initiate this activity or direct the Named Employee to participate in the television Show. All AbbVie employees are provided with mandatory annual ABPI Code Training to ensure all their activities are compliant with the ABPI Code. Slides 14-18 of the training are aimed to give our employees the knowledge to understand that all UK Employees need to comply with the ABPI Code, always maintain high standards, and not promote POMs to the public, even if they are in an international role that is not directly linked to AbbVie's activities on the UK market. We believe AbbVie has taken reasonable and necessary steps to ensure all its UK-based employees receive adequate training, as well as periodic reminders via email, team meetings, and video. The training provided to employees continuously evolves to ensure the learnings of new Code cases, including previous cases involving AbbVie / Allergan, are consistently embedded in our employees' day to day work. For example, the SVP for Allergan Aesthetics and the UK General Managers provided a video training that reinforces that any activity that could be considered promotion of a POM to the public is prohibited.

We also believe the company implemented the appropriate corrective and preventative actions to effectively address this incident in a timely manner and ensure similar incidents do not occur again in the future. Therefore, we do not believe that, against this background of robust training, awareness, and effective "Speak Up" mechanisms, this isolated occurrence could be said to bring discredit or reduce confidence in the pharmaceutical industry as a whole. Considering the above, we believe that clause 2 was not breached.

Clause 3.3

We would like to highlight that the Named Employee did not utilize social media in this Case, as they participated in filming a television Show, which is not a social media platform. Additionally, no AbbVie employee directed any members of the public to the ITV website / Daily Star website. AbbVie's past undertakings related directly to social media usage. Considering the above, we believe that there is no breach of clause 3.3.

Clauses 5.2, 8.1, 12.1, 12.3, and 12.9

The ABPI defines promotion as "*any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines.*" As explained above, AbbVie did not undertake this activity. AbbVie did not instruct,

approve, or endorse the Named Employee to participate in the Show. The Named Employee participated in the Show on their own accord and not as a representative of AbbVie. Additionally, there has been no financial or any other material support for the Show. As there was no involvement of AbbVie, but solely independent actions from the Named Employee, we believe that there is no breach of clauses 5.2, 8.1, 12.1, 12.3, 12.9.

AbbVie thanks the PMCPA for the opportunity to respond to this complaint and we reiterate our continued commitment to ensuring all our employees operate consistently with the highest standards of ethical conduct as we continuously endeavour to comply with the ABPI Code in all our activities.'

PANEL RULING

The complaint related to the appearance of an AbbVie senior global medical affairs employee, based in the United Kingdom, on a popular TV quiz show. The complainant's allegations broadly related to the promotion of a prescription only medicine to the public and a breach of undertaking.

The complainant also referred to an article in the Daily Star which referred to the individual's appearance on the show and cited the senior employee's answer to a question about their career by the host:

'I am [a senior medical employee] for a pharmaceutical and medical device company and predominantly I am across the aesthetics franchise, so injectable products like Botox and facial fillers.

And my background is I'm a qualified facial plastic surgeon and head neck surgeon'.

The Panel noted AbbVie's submission that the participation of the senior employee was not an activity initiated, approved or directed by the company. During AbbVie's investigation, the named employee had explained that they did not communicate their intent to participate in the show, nor did they seek any approval or guidance from AbbVie prior to their participation on the show, as it related to their private/personal life having no relationship to their employment. They also explained that when they made the reference to Botox on the show, they did not plan or aim to promote a prescription only medicine to the general public, rather addressing a general question from the show host around a brief description of their professional experience/background.

It was an established principle under the Code that companies were responsible for the acts and omissions of their employees.

The Panel considered whilst no specific indication was mentioned, the senior employee referred to the aesthetics therapy area and their experience as a plastic surgeon when mentioning Botox. In the Panel's view, the indication for Botox, a prescription only medicine in the UK, was widely known, including to members of the public. The popular quiz show would have been viewed by millions of viewers and in the Panel's view, the senior employee had promoted a prescription only medicine to members of the public. **A breach of Clause 26.1** was ruled, as acknowledged by AbbVie.

The Panel took into account its ruling above and considered when material was available to the public, it needed to comply with the relevant requirements of the Code. Whilst members of the public would include health professionals, in the Panel's view, the television show was not intended as advertising to a health professional audience and the provision of the associated obligatory information would, on that basis, not have been appropriate. The Panel therefore considered that the allegations relating to the promotion to health professionals were not relevant and ruled **no breach of Clauses 8.1, 12.1, 12.3 and 12.9.**

The complainant alleged that the employee's mention of Botox did not reflect the special nature of this medication which was of particular concern given this TV show had 'a regular audience of 3-5 million people'.

Clause 5.2 required that 'all material and activities must recognise the special nature of medicines and respect the professional standing or otherwise of the audience to which they were directed and must not be likely to cause offence'. The Panel considered the employee's mention of Botox on a national television show directed wholly at members of the public failed to recognise the special nature of medicines. In reaching this consideration, the Panel also noted the complainant's concerns with the conduct of the senior employee when 'one of the other contestants played a joke saying: "Well, my colleague [name] would like to place a large order for Botox please...her best potions needed"', to which they were smiling and nodding'. The Panel ruled **a breach of Clause 5.2.**

The Panel considered AbbVie had been let down by its senior employee. AbbVie had been advised of the involvement of their employee in the show on 4th May 2022, shortly after it aired on television on 29th April 2022. The Panel notified AbbVie of the complaint on 30 June 2023 and AbbVie submitted it had sent letters on 14 July 2023 informing the television channel and Daily Star that, among other things, prescription only medicines cannot be advertised to the public; both media outlets were requested to remove all references to Botox from their platforms and in particular the episode and article at issue.

Nonetheless, noting that the employee was a senior member of staff from the medical department and had advertised a prescription only medicine on television to members of the public, the Panel considered high standards had not been maintained and **a breach of Clause 5.1** was ruled, as acknowledged by AbbVie.

The Panel took into account the activity undertaken by AbbVie once it was made aware of the matter including the sanctions and (re/)training mandated to the employee along with the company's internal communications of the incident.

Clause 2 was a sign of particular censure and reserved for such use. The Panel considered that its concerns were adequately covered by its breach rulings above and did not consider that the particular circumstances of this case warranted a breach of Clause 2. The Panel ruled **no breach of Clause 2.**

In relation to the allegation regarding a breach of undertaking, the Panel noted the complainant had not cited the undertaking(s) that AbbVie had allegedly breached; AbbVie submitted its past undertakings related directly to social media usage and that the senior medical employee 'did not utilize social media in this case, as they participated in filming a television show, which is not a social media platform. Additionally, no AbbVie employee directed any members of the public to the ITV website / Daily Star website'. In this regard, the Panel considered the complainant

had not established that AbbVie had breached its undertaking(s) and ruled **no breach of Clause 3.3**.

Consequently, the Panel ruled **no breach of Clause 5.1 and Clause 2** in this regard.

Complaint received **29 June 2023**

Case completed **22 August 2024**